Endovascular repair of peripheral artery aneurysms

Tielliu, Ignace François Jacques

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Ignace Tielliu

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Ignace François Jacques Tielliu

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Promotor:	Prof. dr. R.J. Ploeg
Copromotores:	Dr. J.J.A.M. van den Dungen Dr. E.L.G. Verhoeven
Beoordelingscommissie:	Prof. dr. ir. H.J. Busscher Prof. dr. E.J. van der Jagt Prof. dr. W. Wisselink

Paranimfen: Drs. Bart Appeltans
Drs. Hans Zengerink

Contents

Chapter 1

INTRODUCTION

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Arterial obstructive disease as a result of atherosclerosis and aneurysmal dilatation are the two main diseases that affect large and middle-sized arteries in the human body. Arterial aneurysmal dilatation often occurs in patients with atherosclerosis and both pathologic conditions share common risk factors. For this reason, aneurysms that do not have a specific aetiology, such as a connective tissue disorder, infection, or post-dissection dilatation, are often described as “atherosclerotic” aneurysms. The location of the disease in the vessel wall, however, is different for atherosclerosis as compared to aneurysmal degeneration. In atherosclerosis, lesions are concentrated in the intima, whereas aneurysmal degeneration is located in the media and the adventitia. In addition, the pathologic feature of atherosclerosis is foam-cell formation whereas aneurysmal degeneration is marked by intense oxidative stress, inflammatory infiltration, transmural matrix degradation, and apoptosis and depletion of smooth-muscle cells.[1] As a result of the differences in pathophysiology between atherosclerosis and aneurysmal degeneration, most aneurysms formerly called “atherosclerotic”, can therefore better be described as “nonspecific” or “degenerative” in origin.[2] As the incidence of aneurysmal degeneration is highest in the infrarenal abdominal aorta, this type of aneurysm has been investigated more intensively and serves as the basis of understanding of the pathophysiology of less common aneurysms occurring in other locations in which similar processes have been discovered.[3]

This thesis focuses on the endovascular repair of aneurysms which are localized distally from the aortoiliac bifurcation and are described as “peripheral aneurysms” throughout the text.

Peripheral aneurysms of the lower extremity

Aneurysmal degeneration most commonly occurs in the infrarenal abdominal aorta with a prevalence of 3% to 10% in men >50 years old and varying with the prevalence of risk factors in the population.[4] More peripheral aneurysms, including solitary iliac, popliteal, and femoral aneurysms (in decreasing incidence) are less frequently occurring entities. Using the National 1990 Hospital Discharge Summary Data, which is a complex sample of non-federal short-stay hospitals in the United States, it was shown that the incidence of iliac and femoral/popliteal artery aneurysms in hospitalized American men was 6.58 and 7.39 per 100,000 respectively.[5]

In a Danish study that screened 4,176 abdominal aortic aneurysms, the prevalence of isolated common iliac artery aneurysms was 0.05% in men between 65 and 73 years old.[6] A large autopsy study on 26,251 patients who died in Malmö (Sweden) between 1971 and 1985, found a 0.03% prevalence of isolated iliac artery aneurysms.[7]
The relative incidence of common and internal iliac artery aneurysms has been documented as 80% and 20% respectively, with the external iliac artery almost never involved, for reasons not exactly known.[8] The relative distribution of femoral aneurysms is 80%, 15%, and 5%, for the common, superficial, and deep femoral artery, respectively.[9]
Peripheral lower extremity aneurysms can all exist as solitary aneurysms although they frequently will occur together with aneurysms in another location, especially the abdominal aortic aneurysm. In a series studied by Diwan et al. of 252 male abdominal aortic aneurysms, the incidence of femoral or popliteal aneurysms was 14%.[10] In another study by Graham et al. of 100 profunda femoris artery aneurysms, 85% were associated with an abdominal aortic aneurysm, and 44% with a popliteal artery aneurysm.[11]
The nationwide Swedish vascular registry (Swedvasc) showed that 28.1% of unilateral popliteal artery aneurysms were associated with an abdominal aortic aneurysm, 8.4% with an iliac artery aneurysm and 9.4% with a femoral aneurysm.[12] As a result of the described associations, it is generally recommended to screen all patients with peripheral lower extremity aneurysms for the presence of an abdominal aortic aneurysm and other peripheral aneurysms, especially on the contralateral side, using duplex examination. In addition, it seems wise to screen all patients with an abdominal aortic aneurysm for the presence of peripheral artery aneurysms. The incidence of popliteal artery aneurysms in a population without abdominal aortic aneurysm is very low. As a result of a community-based abdominal aortic aneurysm screening programme, Claridge et al. found three popliteal artery aneurysms in a group of 112 patients with a small abdominal aortic aneurysm and no popliteal artery aneurysm in a group of 171 patients with a normal-sized aorta.[13]
A distinct entity is formed by the iatrogenic pseudoaneurysm in the groin. As a result of a puncture hole in the femoral artery (most often the common femoral artery) after an intraarterial catheterization, arterial blood flows in a virtual space which is the pseudoaneurysm. The wall of the pseudoaneurysm does not contain one single layer of the native artery but is formed

by fibrous tissue. The incidence of femoral postcatheterization pseudo–aneurysms has been reported between 0.05% and 4% and increases with the use of larger sheaths.[14]

Natural history and symptomatology

The natural history of peripheral aneurysms is associated with continuous enlargement. As with abdominal aneurysms, larger peripheral aneurysms seem to grow faster than smaller ones. The average expansion rate of a common iliac artery aneurysm has been calculated to be at least 2.9 mm per year in a series of 104 cases.[15] Others describe an average expansion rate of 0.5 to 1.5 mm per year for aneurysms <3 cm with an increase up to 2.8 mm per year for aneurysms ≥3 cm.[16] In a series of 24 popliteal aneu-rysms described by Pittathankal and Galland et al., growth rates were 1.5 mm, 3.0 mm, and 3.7 mm per year for aneurysms of <20 mm, 20-30 mm, and >30 mm in diameter, respectively.[17] This is in concordance with the study of Stiegler et al. who also reported a doubling of the growth rate for popliteal aneurysms >20 mm in diameter as compared to smaller ones.[18] Unlike for abdominal artery aneurysms, where female sex, smoking, and a higher mean blood pressure were found to be independent risk factors for rupture[19], no such association has been demonstrated for peripheral aneurysms.
Iliac aneurysms are particularly associated with rupture. Due to the anatomical location deep in the pelvis, iliac aneurysms are difficult to detect during clinical examination and will often stay asymptomatic until they rupture. Nevertheless, they can exert compression on adjacent pelvic structures, leading to ureteral obstruction, hematuria, iliac vein thrombosis, large bowel obstruction, and lower extremity neurological deficits. Femoral aneurysms will often be detected by the presence of a palpable mass in the groin or thigh region and eventually lead to pain.[20] Popliteal aneurysms more often will lead to distal ischemia as a result of thrombosis or embolization and rarely present with rupture. The annual complication rate associated with an asymptomatic popliteal artery aneurysm was found to be 14%, increasing to 68% after 5 years.[20,21] Femoral and popliteal aneurysms that are large enough to exert compression on adjacent structures can obviously lead to deep venous thrombosis or a neurological deficit.
Although no clear guidelines have been formulated, the recommended and generally accepted diameter thresholds for intervention in asymptomatic

good-risk and surgically fit patients are the following: 3.5 cm for a common iliac artery aneurysm, although most iliac aneurysms do not rupture until they have reached a diameter of 4 or 5 cm[15]; 3.0 cm for an internal iliac artery aneurysm[22]; 2.5 cm for a common femoral artery aneurysm; 2.5 cm for a superficial femoral artery aneurysm[20]; 2.0 cm for a profunda femoris artery aneurysm[21]; and 2.0 cm for a popliteal artery aneurysm.[18,25-28]
With regard to the popliteal artery, a lot of controversy still exists about the exact diameter cut-off point for treatment, with a gray zone between 2 and 3 cm. Galland et al. have advocated using a combination of aneurysm size and distortion of the popliteal artery as a guideline to treat asymptomatic popliteal aneurysms. The highest predictive value for symptomatology would be a diameter of ≥3 cm and a distortion of >45°, measured as the angle of the most proximal curve in the popliteal artery.[21]
The impact of thrombus in the wall of the aneurysm on the occurrence of symptoms is unclear, although it is reasonable to believe that thrombus may dislodge and cause peripheral embolization. In the Swedvasc registry, 96.6% of the popliteal artery aneurysms had >2 mm of thrombus in the wall of the popliteal artery.[12]

Diagnosis and follow-up

Asymptomatic peripheral aneurysms are nowadays often diagnosed on a computed tomography (CT) scan that was performed for another indication. A clinical suspicion of a peripheral aneurysm can be confirmed by duplex ultrasound examination or by CT or magnetic resonance (MR) angiography. Follow-up of a peripheral aneurysm can best be performed with a duplex ultrasound scan to measure the maximal diameter in a plane perpendicular to the axis of the vessel. In addition, with a duplex scan, the presence of thrombus in the wall of the aneurysm can be visualised. The quality of the inflow and outflow tract can be assessed and ankle/brachial pressure indices measured. Follow-up intervals should be dictated by the expected growth rate of the aneurysm. The exact growth rate of the different types of aneurysms, however, is difficult to predict, is often characterized by a staccato pattern[29], and may be subject to factors as smoking[15] and hypertension.[17] To give recommendations on the ideal follow-up interval for the different aneurysms based on diameter and threshold for intervention is difficult. It should rather be dictated by the individual patient's risk factors, including contralateral disease, aneurysmal disease elsewhere, smoking and hypertension.[29]

Treatment

Historical perspective

Operative treatment of peripheral aneurysms started in the 18th century. The indication for treatment in the early days of surgical practice for peripheral aneurysms was actually to induce thrombosis. Patients presented with pain, swelling of the leg due to venous compression, and rupture of the aneurysm. Thrombosis was induced either by compression or ligation. Different techniques have been described and were dictated by the anatomical location of the aneurysm, either deep in the pelvis (iliac vessels) or located more superficially (femoral or popliteal vessels).

The "Hunterian ligation", performed by John Hunter (St George's Hospital, London) in 1785 on a 45-year-old coachman with a popliteal artery aneurysm was said to be a legendary intervention in those days. It proved to be successful after 15 months when the patient died of other causes and the aneurysm proved to be still thrombosed. In 1817, Sir Astley Paston Cooper (Guy's Hospital, London), who was an apprentice of Hunter, performed the first operation for an iliac artery aneurysm in a 37-year-old man with a traumatic aneurysm of the external iliac artery that was eroding through the skin. He ligated the aorta above the aneurysm. The patient survived the operation but died 40 hours later.[30] Valentine Mott (New York) who had been trained by Cooper in London, performed the first successful operation for a common iliac artery aneurysm in a 33-year-old farmer in 1827. He ligated the proximal iliac artery.[27] Until the 1950's, ligation was the only treatment option for iliac artery aneurysms.[31]

In the 20th century, for popliteal artery aneurysm repair, a reconstruction through a posterior approach with a vein graft interposition was first introduced by Erich Lexer (University of Jena, Germany) in 1912, next by Hogarth Pringle (Glasgow Royal Infirmary) and Bertram Bernheim (Union Protestant Infirmary, Baltimore) in 1915. In 1969, Edwards described for the first time the technique of proximal and distal ligation and reversed saphenous vein bypass grafting through a medial approach.[28]

Current treatment modalities

Since the era of John Hunter and Sir Astley Cooper, not only operative techniques, but also the indications for treatment have evolved. In the early days, symptoms of compression and rupture including pain, obstruction of adjacent structures, and swelling of the limb were indications for treatment. In present times, peripheral aneurysms are primarily treated to prevent all complications mentioned above. Operative techniques have evolved from simple compression and ligation to induce thrombosis to revascularization using a bypass or interposition graft. For this purpose, techniques using autologous material such as the saphenous vein were developed first. Prosthetic graft material was introduced in the 1950's. Stanley Crawford reported in 1958 the use of Dacron as bypass material to treat popliteal artery aneurysms.[32]
In the last decade of the 20th century, the rapid evolution towards endovascular techniques using covered stents, which are introduced through the common femoral artery, has changed the surgical landscape of peripheral aneurysm repair significantly.

Treatment of iliac artery aneurysms

Open surgical repair

Open surgical treatment of iliac artery aneurysms is still a challenge for the 21st century vascular surgeon. Often, the location of the iliac artery is deep in the pelvis, complicated by adjacent structures as deep veins, the ureter, and on the left side by the overlying sigmoid colon. These anatomical configurations make an intervention in this area difficult and prone to complications. In case of an aortoiliac aneurysm, reconstruction through a midline laparotomy is still preferred, although some do advocate a retroperitoneal approach, especially for high-risk patients.[33] An aortobiiliac bypass graft is constructed, preferably by landing on the iliac bifurcation. In case of an aneurysmatic iliac bifurcation or internal iliac artery, the distal anastomosis is constructed on the external iliac artery or, in case of severe atherosclerosis, even on the common femoral artery through a separate groin incision. For solitary unilateral aneurysms of the common or internal iliac artery, a retroperitoneal approach through an incision in the lower flank is preferred.[30,34]

The aneurysm is opened and an interposition graft is constructed. When a large internal iliac artery aneurysm is present, the distal branches of the internal iliac artery are ligated from the outside or over sewn from the inside after opening the aneurysm, followed by an interposition graft between common and external iliac artery.

Endovascular repair

For endovascular repair of iliac artery aneurysms there are basically two options. An endovascular aortobiiliac bifurcation graft (or aortouniiliac stent-graft with crossover bypass graft) is used to treat aortoiliac aneurysms and solitary iliac aneurysms with a too short or absent proximal landing zone to be treated with a single stent-graft in the iliac artery. For solitary common and/or internal iliac artery aneurysms with a proximal neck suitable as proximal landing zone, a stent-graft is positioned in the iliac artery, starting at the aortic bifurcation and landing distally in the distal common iliac artery, provided there is a suitable landing zone, or else in the external iliac artery.
In 1998, and still at the beginning of the endovascular era, Krupski et al. wrote that 'endovascular repair may be less durable and effective than direct surgical repair'.[30] Since then, however, endovascular techniques have flourished, also for the treatment of iliac artery aneurysms and some aspects of this evolution are illustrated in this thesis.

The internal iliac artery

The fate of the internal iliac artery is an important issue in iliac aneurysm repair. Occlusion of the internal iliac artery can result in pelvic ischemic complications with both buttock claudication and erectile dysfunction being most prevalent. Bladder dysfunction, sacral decubitus ulceration, colonic ischemia, spinal cord ischemia, and scrotal skin sloughing also can occur. The debate as regards the incidence and clinical significance of internal iliac artery occlusion is still ongoing. Especially the difference in outcome between unilateral and bilateral occlusion and between embolization versus simple overstenting of the internal iliac artery is still not clear.[35] Lin et al. recently reviewed the literature regarding the treatment of solitary iliac aneurysms from 2000 to 2008 and found that buttock claudication appeared with an incidence of 28% (198/706) for unilateral and of 42% (43/102) for bilateral internal iliac artery occlusion. New onset erectile dysfunction emerged in 19% (29/152) for unilateral and in 24% (17/70) for bilateral internal iliac artery occlusion. The incidence of colonic ischemia after endovascular abdominal aneurysm repair (EVAR) and internal iliac artery occlusion was increased with an overall incidence of 3.4%. After solitary iliac aneurysm repair, this incidence must be lower because the inferior mesenteric artery is not compromised. The risk of spinal cord ischemia after internal iliac artery occlusion is <0.1%.[35]

When trying to predict the occurrence of adverse effects of internal iliac artery occlusion, it is important to understand that the circumflex branches of the common femoral artery and branches of the profunda femoris artery provide greater collateral circulation than the contralateral internal iliac artery.[35,36] In addition, risk factors for complications after internal iliac artery occlusion are younger age and bad left ventricular function.[37] Other risk factors predictive for symptoms of ischemia after internal iliac artery occlusion were found to be >70% stenosis of the contralateral internal iliac artery, absence of filling of three or more named hypogastric branches, and diseased or absent ascending branches of the ipsilateral femoral artery.[38] Also, patency of the inferior mesenteric artery, the subclavian artery, and previous history of abdominal or thoracic aneurysm repair, either open or endovascular, must be considered before the decision is taken to occlude one or both internal iliac arteries.[39]

Occlusion of the internal iliac artery can be established by embolization or by simply overstenting the origin of the artery. Embolization can be performed with coils or with a plug (e.g. Amplatzer vascular plug, AGA Medical Co., Plymouth, Minn, USA), both preferably positioned in the proximal part of the internal iliac artery so as not to overstent and occlude the origin of the branches and thereby compromizing collateral flow.[40] Overstenting alone may be performed when there is circumferential apposition of the stent-graft to the wall of the artery at the level of the origin of the internal iliac artery. A type II endoleak, which may result from back bleeding from the internal iliac artery, can at that point in time, however, not be solved in an endovascular way.

In endovascular abdominal aneurysm repair (EVAR), no benefit has been shown of sequential as compared to simultaneous (i.e. at the time of aneurysm exclusion) internal iliac artery embolization.[40]

For the preservation of the internal iliac artery in iliac aneurysm repair, different techniques have been developed. With the hypogastric artery bypass, an endograft is introduced from the ipsilateral common femoral artery and positioned from the external to the internal iliac artery, combined with a contralateral aortouniiliac endograft and a surgical crossover bypass.[41,42] Antegrade hypogastric stent-grafting combined with a surgical crossover bypass[20] and relocation of the iliac bifurcation are other solutions.[43] Finally, the iliac branched device (IBD) which constitutes of a bifurcated endograft for the common iliac artery with an incorporated branch for the internal iliac artery, is the only totally endovascular option to spare the internal iliac artery. This technique will be discussed in detail in this thesis.

Treatment of femoral artery aneurysms

Common femoral artery aneurysms are in general treated by open surgery with an interposition graft from the distal external iliac artery or proximal common femoral artery to the superficial femoral and/or profunda femoris artery. The main reason for which the common femoral artery aneurysm is generally not treated with a stent-graft is that the femoral bifurcation is often involved in the aneurysm and therefore either profunda femoris or superficial femoral artery would be sacrificed.

For a profunda femoris artery aneurysm, a femoral interposition graft is the preferred treatment above ligation alone, in view of the frequent preexistent superficial femoral artery occlusion in these cases.[24] Endovascular repair is anecdotal but feasible in selected cases with proximal and distal landing zones, away from the femoral artery bifurcation.[44,45]

For a superficial femoral artery aneurysm, an interposition graft or bypass with proximal and distal ligation can be constructed. Endovascular therapy is feasible and seven cases treated with a Wallgraft (Boston Scientific, Natick, Mass, USA) have been reported with a 100% patency after 1 year.[46]

For postcatheterization false aneurysms of the groin, open repair was the gold standard up till 1991. At that time, ultrasound scan-guided compression was introduced. This technique was a painful exercise for both patient and laboratory technician, and it was time consuming. Ultrasound scan-guided thrombin injection was introduced in 1986 by Cope and Zeit but became popular only years later. With ultrasound scan guidance and as an outpatient procedure, a concentrated solution of thrombin is injected in the pseudoaneurysm, after which thrombosis of the aneurysm and sealing of the puncture hole immediately follow. Antiplatelet therapy or oral anti–coagulation is not a contraindication and does not limit clot formation. It is an almost painless and relatively costeffective and durable procedure. It has become the new gold standard for treatment of femoral postcatheterization pseudoaneurysms.[47]

Treatment of popliteal artery aneurysms

Open surgical repair

In contrast to the concept in the era of John Hunter, popliteal artery aneu–rysms are nowadays treated to prevent both the effects of chronic silent embolization and acute embolization or thrombosis. Both situations will eventually lead to some degree of limb ischemia, such as claudication or critical ischemia. All popliteal aneurysms contain thrombus to a certain degree, which depends on the size of the aneurysm.[12,48,49] It is reasonable to think that thrombus in the wall of the aneurysm will be the source of the emboli. Evidence that only aneurysms with a proven thrombus in the wall are at a high risk for embolization or thrombosis, however, is scarce.[49]

Type of approach and type of conduit

Open repair is still considered the gold standard. The different surgical techniques for exclusion of a popliteal artery aneurysm can be divided into two groups. One is construction of a bypass via a medial approach after proximal and distal ligation of the popliteal artery. The other is an interposition graft after aneurysmectomy via a posterior approach.
With the standard medial approach, the popliteal artery is ligated proximally and distally to the aneurysm, and a bypass is constructed through a medial above-knee and below-knee incision. Bypasses start preferably from the above-knee superficial femoral artery to keep the bypass as short as possible. In cases where the superficial femoral artery is degenerated with aneurysmal dilatation or stenosis, a long bypass originating from the common femoral artery can be constructed. The distal anastomosis is usually performed onto the distal popliteal artery. When aneurysmal dilatation extends onto the tibioperoneal trunk or stenosis is present at that level, the distal anastomosis is made onto the peroneal or one of the tibial vessels.

With the medial approach, side branches cannot always be controlled unless a large incision over the knee joint is made with transection of the tendons of the pes anserinus and the semimembranosus muscle.
The posterior approach is used less frequently than the medial one. In a large Swedish registry, only 8.7% (60/717) of popliteal artery aneurysms were treated via a posterior approach.[12] With the patient in a prone position, and usually through an S-shaped incision with the upper limb of the incision on the medial side and the lower limb in between the two heads of the gastrocnemius muscles, the popliteal artery is dissected free with care of the tibial and peroneal nerves and the popliteal veins. Arterial and nerve branches to the medial head of the gastrocnemius muscle that cross the popliteal space from lateral to medial often have to be transsected. The arteries above and below the popliteal artery aneurysm are clamped and the aneurysm is opened, side branches are over sewn from within the aneurysm, and an interposition graft is constructed with end-to-end anastomoses. Good results have also been reported using a straight incision instead of an S-shaped curvilinear incision.[50] The posterior approach provides a limited proximal access only up to the level of the adductor hiatus and is therefore not indicated for large aneurysms that extend beyond the hiatus. Distally, the trifurcation vessels can be exposed by dissection between the medial and lateral heads of the gastrocnemius muscle, although a medial approach with venous bypass is to be preferred when the distal anastomosis is on the tibial or peroneal vessels.
For both types of reconstruction, via the medial or the posterior approach, autologous venous grafts and prosthetic grafts are used. Harvesting the long saphenous vein is, however, easier through a medial approach. Venous reconstruction with the posterior approach using the long saphenous vein necessitates either two separate incisions and turning the patient's position during the operation, or the use of the short saphenous vein.
Beseth and Moore have described a series where only the posterior ap–proach was used for repair of 30 popliteal artery aneurysms with a prosthetic graft (6 mm Dacron or 6 to 8 mm polytetrafluoroethylene (PTFE)).[50] Primary patency after 2 years was 92%. The authors state that they only used a medial approach with a venous graft when the aneurysm extended beyond the hiatus and when the distal anastomosis was onto the trifurcation vessels. One explanation for the good results in this series could be the relatively short length of the bypass.[51] In a multicenter case-matched study

comparing the medial and posterior approaches (33 posterior versus 33 medial), Kropman et al. found that primary patency at 1 and 4 years was 79% and 66% for the posterior approach and 93% ($P < 0.05$) and 69% (P = NS) for the medial approach after a mean follow-up of 47 months.[48] In addition, irrespective of approach, venous reconstructions resulted in significantly higher primary patency rates compared with prosthetic reconstructions at 3-year follow-up (84% versus 67%; $P < 0.01$).[52] The Swedvasc registry demonstrated a primary patency rate at 1 year with venous and prosthetic bypass grafts of 90% and 72% respectively ($P < 0.001$).[12] This can be explained by the fact that longer bypasses give better results with vein than with prosthetic grafts.[51]

Results after elective surgical repair

The elective repair of an asymptomatic popliteal artery aneurysm is often mentioned as being associated with excellent results.[53] For asymptomatic cases only, 5-year patency rates vary between 78% and 86%.[54-56] Most series, however, report combined results for symptomatic and asymptomatic cases, with 5-year primary patency rates of between 60% and 86%.[14,51-55,57-60] Limb salvage rates for elective cases vary between 93% and 100%, indicating that surgical popliteal artery aeurysm repair is not without risk.[54-56] Primary patency rates at 10 years also vary considerably between studies and have been reported as low as 66% for elective cases.[53]
In the various reports on open repair of popliteal artery aneurysms, only limited data are available on complications including saphenous nerve injuries for medial approaches, tibial and peroneal nerve injuries for posterior approaches, excessive blood loss due to injuries to the deep veins during dissection, postoperative deep venous thrombosis, lymph leakage, and wound healing problems. Morbidity as a result of these complications has to be taken into account when comparing open and endovascular treatment. In a series by Kropman et al. early (30 day) complications occurred in 21% of the cases, for both the medial and posterior approach (n = 33 in both groups).[52] Risk factors for amputation after open repair are poor run off, urgent treatment, age above 70 years, and the use of a prosthetic graft.[12]

Continuous aneurysmal sac flow and growth

The exclusion of a popliteal artery aneurysm through a medial approach carries a risk for continuous collateral flow and growth of the aneurysm through backflow from genicular side branches originating from the aneurysm. Ravn et al. reported a 33% (57/174) incidence of continuous aneurysm perfusion after repair via a medial approach, with 88% of the cases becoming symptomatic and 14% requiring reoperation.[12] The authors noted that, especially after a long bypass originating from the common femoral artery, proximal ligation was often not performed. In contrast, with the posterior approach, 8.3% (2/24) of the aneurysms had expanded at re-examination and there were no reoperations for expansion.[12] Kirkpatrick et al. reported continuous aneurysm flow in 30% (12/36) of the cases, with growth in 50% after a 48-month follow-up.[61] Mehta et al. reported 38% (10/26) of cases showing flow in the aneurysmal sac after a follow-up of 38 months, with 23% demonstrating growth of the aneurysm and 12% ruptures.[58] Some authors therefore concluded that double ligation of the artery both proximally and distally has to be performed as close as possible to the popliteal artery aneurysm in order to achieve complete exclusion of the aneurysm.[12,58,59,61,62,] Even then, collaterals originating from the aneurysm itself can be the source of continuous sac flow. Especially with the medial approach these collaterals are difficult to ligate.

Endovascular repair

The endovascular repair of a popliteal artery aneurysm was first mentioned in 1994. Marin et al. used a polytetrafluoroethylene (PTFE) bypass with a stent attached on both ends to secure the graft in the popliteal artery above and below the aneurysm.[63] Numerous commercial stent-grafts have been developed since then and used to treat popliteal artery aneurysms. To place a stent-graft in the popliteal artery that is subject to repetitive flexion-extension movements requires radial force for apposition of the graft to the wall of the artery and to prevent migration. Flexibility to prevent kinking, and a specific design to prevent fracture of the stent material are other features of the ideal stent-graft. Description of the endovascular repair of popliteal artery aneurysms with the Hemobahn/Viabahn stent-graft, results and outcome of the procedure, and a review of the literature, are described in this thesis in detail.

Emergency repair

Emergency repair is a predictor of worse outcome after surgical popliteal aneurysm repair compared with elective repair, with 5-year primary patency rates of between 49% and 65% and limb salvage rates no higher than 64%.[54-56] In the Swedvasc registry, 235 patients (33%) treated for acute ischemia between 1987 and 2002 had a higher risk for amputation than the patients who were treated electively.[12] The amputation rate at 1 year had decreased gradually since 1987 and was 5.4% for the period 1998 to 2002. This may reflect the increased use of pre-operative thrombolysis over the years.[12]
Intra-arterial thrombolysis is recommended as preoperative adjunct to recanalize the tibial vessels in case of an acutely thrombosed popliteal artery aneurysm. The choice between preoperative thrombolysis followed by a semiacute reconstruction, and intraoperative thrombolysis, however, is still controversial. Galland et al. demonstrated that preoperative intra-arterial thrombolysis was associated with an increased risk for embolization of thrombus and acute ischemic deterioration in up to 13% of the cases compared with intraoperative lysis.[64] The authors favour infusing the lytic agent during construction of the proximal anastomosis. In contrast, Ravn et al. found that the risk of amputation was lower in patients treated with preoperative thrombolysis than in those who received immediate surgical repair with adjunctive intraoperative thrombolysis.[12] Some have successfully experimented with intraoperative isolated perfusion of lytic agents.[65]
Despite thrombolysis, however, in some cases fragments will have embolized that cannot be lysed or removed during the subsequent intervention. In these cases, permanent loss of sensory or motory function will ensue or it will lead to amputation of the limb.[28]

Conclusion

Peripheral artery aneurysms, defined in this thesis as aneurysms located distally from the aortic bifurcation, are rare entities. When they become symptomatic and lead to thrombosis, embolization or rupture, however, they can lead to severe morbidity and mortality. Therefore, patients with peripheral aneurysms nowadays ought to be treated before symptoms will occur. In the different paragraphs of this introduction, an overview was given which concerns past and presence of open surgical repair. In the following chapters of this thesis, a number of different aspects of the endovascular repair of peripheral aneurysms will be described in detail.

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Chapter 2

DESIGN AND RATIONALE OF THE THESIS

In this thesis, peripheral artery aneurysms are defined as solitary aneurysms that are located below the aortic bifurcation as compared to more centrally located aortic or aortoiliac aneurysms. Thus, the thesis focuses on aneu–rysms of the iliac and popliteal artery, as they are by far more prevalent compared to aneurysms of the femoral arteries.

The indication for treatment of iliac aneurysms is mainly based on the chance of sudden rupture, which is associated with morbidity and mortality. Popliteal aneurysms, on the contrary, rarely do rupture but tend to thrombose instead or turn out to be sources of acute or chronic peripheral embolization, both often leading to acute limb ischemia.

Traditionally, iliac and popliteal artery aneurysms have been treated by open repair. Starting at the beginning of the 1990's, the ongoing evolution in endovascular technology made it possible to treat peripheral aneurysms with a stent-graft. These stent-grafts incorporate a sealing fabric as well as a skeleton made of a metal or alloy stent material. The skeleton provides the radial force needed for apposition of the stent-graft to the wall of the artery and for fixation, but it also bears the potential to kink when a stent-graft is positioned in tortuous vessels, and to fracture when positioned at a hinge point of the artery.

This thesis is divided in two sections. In the first section, the endovascular treatment of iliac artery aneurysms is analyzed. The second section will focus on the endovascular treatment of popliteal artery aneurysms in particular.

Section I
The endovascular treatment of iliac artery aneurysms

A challenging issue for endovascular iliac aneurysm repair includes dealing with the often tortuous character of the iliac vessels. Iliac arteries not only follow the natural curve of the pelvis, but also tend to elongate when becoming aneurysmatic. Another issue of importance is the mismatch in diameter between the common and external iliac artery that often precludes the use of a cylindrical stent-graft. The design of the stent-graft is therefore important to adequately manage tortuosity and diameter mismatch. The results of a cohort study of solitary iliac artery aneurysms which were treated with a funnel-shaped stent-graft made of a nitinol stent and an inner lining of expanded polytetrafluoroethylene (PTFE), as well as an overview of the literature on iliac stent-grafting, are presented in **Chapter 3**.

Another item specifically associated with iliac aneurysm repair is the fate of the internal iliac artery. Common iliac artery aneurysms oftentimes extend up to or include the origin of the internal iliac artery. In those cases, the internal iliac artery must be overstented in order to assure adequate sealing in the external iliac artery. In cases where the aneurysm incorporates the origin of the internal iliac artery, this vessel is additionally and intentionally occluded with coils or with a plug to prevent a so-called endoleak resulting from back bleeding from the internal iliac artery into the aneurysm sac. To try to overcome the negative effects of internal iliac occlusion several techniques, most of them combining open and endovascular surgery, have been developed to preserve internal iliac perfusion.
In contrast with the open surgical techniques to spare the internal iliac artery, the iliac branched device assures internal iliac artery perfusion and is introduced by endovascular means only. The pioneering results of a cohort study of endovascular iliac aneurysm repair with the iliac branched device are reported in **Chapter 4**. The iliac branched device incorporates a preloaded indwelling guide wire that passes through the internal iliac branch. This indwelling wire can be snared from the contralateral femoral access side. This through-and-through crossover wire enables the advancement of a stent-graft from the contralateral side to bridge the gap between the iliac branch and the internal iliac artery. For the introduction of this bridging stent-graft a stable position of the crossover sheath is mandatory. Therefore, it has been advized to keep the through-and-through indwelling wire in position until the bridging stent-graft is in place. This requires working with parallel wires through one sheath, and can cause problems as a result of friction and entangling. Ongoing experience allowed us to develop an alternative easier and safer technique for introduction and deployment of the iliac branched device. This modified technique using “tromboned” sheaths is described in detail in **Chapter 5**.

Section II
The endovascular treatment of popliteal artery aneurysms

The most important challenge in endovascular popliteal aneurysm repair is how to cope with effects of repetitive bending at the level of the hinge point of the popliteal artery. In addition, as in iliac aneurysm repair, the diameter mismatch between the proximal and distal landing zone is a matter of concern. Again, design of the stent-graft and ability to handle these aspects are important issues. For popliteal aneurysm repair we deliberately chose a flexible stent-graft with a nitinol skeleton and expanded polytetrafluoroethylene (PTFE) fabric lining at the luminal side. The pioneering results of a cohort study of popliteal artery aneurysms treated with this type of stent-graft are presented in **Chapter 6**.

A stent-graft crossing a flexible joint such as the knee that is subject to repetitive flexion-extension movements is prone to complications. In addition, it is often necessary to use multiple stent-grafts to cover the lesion including proximal and distal landing zones. The flexibility of the knee joint and the need for multiple overlapping stent-grafts are both the basis of technical problems or complications. The effect of the learning curve on outcome of popliteal stent-grafting and including the occurrence of occlusions, migrations, stent fractures, and stenoses, was the subject of the study that is outlined in **Chapter 7**.

As mentioned before, the hinge point of the popliteal artery in a highly flexible knee joint is the basis of reluctancy among many vascular surgeons and interventional radiologists to use stent-grafts in this area. An increasing cumulative number of stent fractures was observed in the cohort of popliteal artery aneurysms after endovascular repair over the years. This warranted a new study on basically the same cohort of popliteal aneurysms as described in chapter 7 and focussing specifically on the occurrence of stent fractures. This study is outlined in **Chapter 8.**

In **Chapter 9**, the results of the different studies are summarized and some perspectives towards future development are discussed.

Section I

ENDOVASCULAR TREATMENT OF ILIAC ARTERY ANEURYSMS

Chapter 3

ENDOVASCULAR TREATMENT OF ILIAC ARTERY ANEURYSMS WITH A TUBULAR STENT-GRAFT: MID-TERM RESULTS

Ignace F Tielliu, Eric L Verhoeven, Clark J Zeebregts, Ted R Prins, Björn I Oranen, Jan J van den Dungen

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Introduction

Iliac artery aneurysms (IAA) occur much more rarely than abdominal aortic aneurysms (AAA). A distinction can be made between true and anastomotic IAA. True IAA are most frequently atherosclerotic and localized in the common iliac artery (CIA), solitary or in combination with an AAA.[1] Solitary IAA were found to occur with an incidence of 0.03% in a large autopsy study.[2] Anastomotic IAA can occur after previous arterial reconstructions, with a cumulative incidence of >20% after a follow-up of 15 years.[3] As a result of the ongoing evolution in imaging techniques, asymptomatic IAA are now being diagnosed more frequently than they were before. They can become symptomatic as a result of compression on or erosion of adjacent structures. The most devastating complication is rupture of the aneurysm, which is difficult to diagnose because usually no pulsatile mass is palpable. To prevent these complications, isolated IAA with a diameter of >3 cm are recommended for elective repair.[1,4]

Open repair of an IAA is a major intervention. The mortality is comparable to that of elective repair of open AAA, and increases up to 33% for emergent interventions. The close anatomic relation of veins and ureters with the iliac arteries in the pelvic region results in a risk of damage to these structures, contributing to the morbidity of the procedure.[1,3,4]

Minimally invasive endovascular repair with a stent-graft may be a good alternative treatment for open repair, with less associated mortality and morbidity. We analyzed a prospective cohort of patients treated endovascularly for an IAA.

Patients and methods

Patient selection

All patients with IAA referred to our university vascular center between June 1998 and June 2005 were evaluated for endovascular repair. Criteria for repair were a diameter of ≥30 mm for anastomotic aneurysms and ≥35 mm for true aneurysms. Inclusion criteria for endovascular repair with a tubular graft included an anastomotic or true aneurysm of the CIA with a proximal neck of ≥1 cm in length, a distal landing zone without significant stenosis or aneurysmal dilatation in the distal CIA or external iliac artery (EIA), and access vessels with a diameter of ≥6 mm. All patients with a concomitant AAA were excluded from this study.

Endovascular procedure

The work-up consisted of a computed tomography (CT) scan. In some cases, an additional calibrated angiography was performed to aid in the necessary measurement and assessment of inflow and outflow tracts.
All procedures were performed in an operating theatre by an endovascular team that included a vascular surgeon and radiologist. Access to the common femoral artery was achieved by open dissection of the groin, preferentially under local anesthesia. A description of this technique using local anesthesia and the criteria for choosing local anesthesia instead of regional or general anesthesia have been described.[5]
Different types of stent-grafts were used, including the Excluder contra–lateral limb (W.L. Gore & Associates, Flagstaff, Ariz, USA), Passager (Boston Scientific, Watertown, Mass, USA), Wallgraft (Boston Scientific, Natick, Mass), and Hemobahn (W.L. Gore). In July 1999, the Excluder bifurcated system was introduced in our practice for the repair of AAA. From October 2000 on, the Excluder contralateral limb stent-graft was preferentially used for the treatment of IAA (Figure 1).

Figure 1. Excluder contralateral limb stent-graft (W.L. Gore).

Embolization of the internal iliac artery (IIA) was performed in those cases where backflow from the IIA was expected to result in a type II endoleak. In cases where embolization of the IIA was needed, it was preferentially performed via the ipsilateral side, or from the contralateral side if judged necessary. Embolization was performed at the origin of the IIA to preserve flow in the different distal branches. It was performed during the same procedure, immediately preceding the endovascular aneurysm repair.

Follow-up schedule

Duplex ultrasound scanning and plain radiographs of the abdomen in anteroposterior and lateral view were made at discharge, 6 months, 1 year, and yearly thereafter. A CT scan (or angiography on some occasions) was reserved for those patients where the ultrasound scan failed or demonstrated an endoleak or growth without endoleak.[6]
All patients received antiplatelet or anticoagulation therapy. Patients who were taking anticoagulants before the intervention, mostly for cardiac indications, continued this therapy after the operation. The other patients were prescribed acetylsalicylic acid, 80 mg daily.

Statistical analysis

Data for continuous variables were expressed as mean ± standard deviation. Data were prospectively collected and analyzed in a retrospective manner. Primary outcome measures were exclusion of the IAA, graft patency, and 30-day mortality. Other outcome measures studied were duration of the procedure, length of hospital stay, and early and late postoperative complications. Time-to-event variables were studied with Kaplan-Meier survival analysis using the Statistical Package for the Social Sciences (SPSS) version 12.0 software (SPSS, Chicago, Ill, USA).

Results

Fifty-eight patients with one or more isolated IAA were evaluated for endovascular treatment, and 21 were not treated endovascularly for different reasons (Table 1). The other 37 patients were treated with a stent-graft. Two of these patients were excluded from this study, including one who was treated with a bifurcated graft, and another with an aortouniiliac device (Table 1).

In the remaining 35 patients, 33 men (94%) and 2 women (6%), 40 IAA were treated with an endovascular tubular stent-graft. Five patients were treated for a bilateral IAA, of which three patients were in the same operation session. Mean age of the patients was 71.3 ± 8.4 years (range, 51 to 85 years). Mean diameter of the aneurysms was 44.2 ± 13.8 mm (range, 30 to 91 mm). Aneurysms were anastomotic in 26 cases and true in 14 cases. Details of the different types of aneurysms are described in Table 2. Elective treatment was performed in 30 patients (86%) and emergent repair in five (14%). Local anesthesia was used for the treatment of 26 patients (74%) and regional or general anesthesia for the treatment of 9 (26%). Four of the five aneurysms that were treated emergently were done under local anesthesia. The four different types of stent-grafts used were the Excluder contralateral limb (n = 28, 70%), Passager (n = 9, 22.5%), Hemobahn (n = 2, 5%), and Wallgraft (n = 1, 2.5%).

Table 1. Details of the 23 patients who were not treated with an endovascular tubular stent-graft.

Treatment	**Criteria for exclusion from endovascular repair**	**n**
Open		
	Short proximal neck	15
	Access vessel stenosis	3
	Choice of patient	1
	Choice of doctor*	1
Endovascular		
Bifurcated	Bilateral IAA with short proximal neck	1
Aortouniiliac	Short proximal neck†	1
Not treated	Died on waiting list (myocardial infarction)	1
Total		**23**

IAA, iliac artery aneurysm.

* young patient with bilateral IAA and patent internal iliac arteries which would have been sacrificed in case of endovascular treatment.

† anastomotic aneurysm of the common iliac artery (CIA) 30 years after endarterectomy and patch. Repair was done with an aortouniiliac stent-graft to the contralateral CIA with preservation of the internal iliac artery (IIA), femorofemoral crossover bypass graft and ipsilateral occluder stent-graft with preservation of the ipsilateral IIA.

Table 2. Details of different types of iliac artery aneurysms treated with a stent-graft.

Type and localization	n	%
True aneurysm	14	35.0
CIA	6	15.0
CIA after aortic tube	5	12.5
CIA after bifurcation on EIA	3	7.5
False aneurysm	26	65.0
CIA after bifurcation on CIA	18	45.0
CIA after bifurcation on EIA	6	15.0
After iliofemoral bypass	1	2.5
CIA after endarterectomy and patch CIA	1	2.5
Total	**40**	**100**

CIA, common iliac artery; *EIA*, external iliac artery.

All procedures were successful, but intraoperative technical problems occurred in four patients. In all four, the stent-graft was positioned too low, and an additional device had to be inserted to seal more proximally.

Additional planned procedures were performed in the same session in six patients, including coil embolization of a native aortoiliac system (n = 1), percutaneous transluminal angioplasty of a femorofemoral crossover bypass (n = 1), interposition graft of the common femoral artery (n = 2), profunda plasty (n = 1), and correction of an inguinal hernia (n = 1). The mean operation time without time needed to perform these additional procedures, but including time needed for embolization of the IIA in some cases, was 83 ± 28 minutes (range, 50 to 150 minutes). No other procedure-related complications occurred, except for those that were mentioned.

The IIA was preserved in two cases (5%), was already occluded at the time of the intervention in 10 (25%), and was intentionally occluded in 28 cases (70%). Occlusion of the IIA was performed by coil embolization in 15 (54%), by covering the origin of the IIA with the stent-graft in 12 (43%), or by open ligation in a patient (3%) with an anastomotic aneurysm on the CIA and an aneurysm of the IIA. Of these 28 patients, 20 did not have a contralateral occlusion of the IIA. Gluteal claudication developed in two (10%). Eight patients had a contralateral occlusion, and in only one of them (13%) did gluteal claudication develop. No other ischemic complications occurred as a result of intentional occlusion of the IIA.

In one patient, an anastomotic aneurysm of a bifurcation leg onto the EIA proved not to be excluded on the first postoperative day.

Table 3. Literature overview of reports on endovascular treatment of iliac artery aneurysms, published from 1999 on.

Author, year	Aneurysms (n)	Type of stent-graft (n)	Mean follow-up period (months) (range)	No. (%) of complications	30-day Mortality (%)
Parsons,[7] 1999	25	PTFE + Palmaz (25)	24	4/25 (16%)	0
Sanchez,[8] 1999	40	PTFE + Palmaz (37); CORV (3)	18 (1-51)	9/40 (23%)	0
Scheinert,[9] 2000	48	CES (37); Pass (6); WG (5)	35 (16-55)	3/48 (6%)	0
Cormier,[10] 2000	34	Pass (34)	15 (2-30)	4/34 (12%)	0
Fahrni,[11] 2003	19	Tube: Excl (8), CORV (1); Bifurcation: Excl (6), V (2) Gianturco coils (2)	21	4/19 (21%)	0
Casana,[12] 2003	16	Nitinol stent-graft (15); LP (1)	18 (3-52)	0	0
This study, 2005	40	Tube: Excl (28); P (9); HB (2); WG (1)	31 (3-83)	3/40 (8%)	0
Total	**222**			**27/222 (12%)**	**0**

PTFE, polytetrafluoroethylene; *CORV*, Corvita (Schneider/Boston Scientific, Natick, Mass, USA); *CES*, Cragg Endopro system 1 (Mintec, Freeport, The Bahamas); *Pass*, Passager (Boston Scientific, Watertown, Mass); *WG*: Wallgraft (Boston Scientific, Natick, Mass); *Excl*, Excluder (W.L. Gore, Flagstaff, Ariz, USA); *V*, Vanguard (Boston Scientific, Watertown, Mass); *LP*, Lifepath (Baxter, Morton Grove, Ill, USA); *HB*, Hemobahn (W.L. Gore);

Expansive pulsations were felt, and a significant endoleak was found on duplex examination. The aneurysm was fed by the ipsilateral patent native aortoiliac system. Exclusion of the aneurysm was eventually established by embolization of the proximal native EIA. This was achieved through a catheter coming up via the bypass graft into the aorta and then going down the native aortoiliac system past the ipsilateral iliac bifurcation.

Other complications included a prolonged ileus that resolved spontaneously (n = 1), urinary tract infection (n = 1), retention bladder (n = 1), and temporary deterioration of renal function (n = 1).

Mean hospital stay was 3.3 ± 2.3 days (range, 1 to 12 days). There was no 30-day mortality. Patients were followed up for a mean of 31.2 ± 20.7 months (range, 3 to 83 months). Complications during follow-up occurred in two patients. A proximal type I endoleak developed in one as a result of stent-graft migration. It was initially positioned to treat an anastomotic aneurysm of a bifurcation limb onto the CIA. The proximal sealing zone was too short, and this resulted in migration and endoleak after 46 months. Treatment consisted of a proximal extension. In another patient, a Passager stent-graft was positioned proximally in an angulated neck to treat a CIA aneurysm. The stent-graft occluded 1 month after the procedure.

Treatment consisted of a femorofemoral crossover bypass.
The mean IAA diameter decreased from 44.9 mm (range, 30 to 91 mm) to 31.9 mm (range, 12 to 53 mm). In one patient, a duplex examination showed an anastomotic aneurysm at the level of the CIA after a bifurcation that grew from 38 to 45 mm without endoleak. This patient is scheduled to undergo further CT scanning.
Ten patients (25%) died after a mean of 26.5 ± 22.2 months (range, 4 to 65 months) of causes not related to the intervention.

Discussion

This study shows that endovascular treatment of IAA with a tubular stent-graft is associated with low mortality and morbidity. In this series with elective and emergent cases, as in other series (Table 3), no procedure-related mortality was noted. The patency rate of 97.5% (1 occlusion) is in accordance with other reports, both endovascular and open.[1,7-13] Most of the patients were operated on under local anesthesia. Complications occurred in 7.5% of the cases (3 of the 40 aneurysms), including one aneurysm that was not immediately excluded, one migration with endoleak, and one stent-graft occlusion.
In 1998 Krupski et al., in a report in the Journal of Vascular Surgery, stated that open reconstruction was the preferred treatment for IAA. This statement was based on a series of 29 open reconstructions and only two endovascular repairs with poor outcome. One was an endovascular stent-grafting and the other an endovascular coil embolization.[1]
Since then, however, several reports have been published describing good results after endovascular repair (Table 3).[7-12] Different types of stent-grafts were used to treat the patients in these studies. In the early reports, homemade devices were used. For that purpose polytetrafluoroethylene (PTFE) grafts were secured with Palmaz stents attached to the proximal and distal end of the prosthesis. Later, several stent-grafts became commer–cially available and in addition to AAA repair, were also used for the exclusion of IAA.
Iliac arteries are often tortuous, even more so when they are aneurysmatic. In addition, the diameter of the proximal sealing zone is often significantly larger than the diameter of the distal sealing zone, which is the EIA in most cases. A funnel-shaped, flexible stent-graft is therefore required. In our view,

the contralateral limb of the Excluder endovascular bifurcated graft is an optimal solution. It is a funnel-shaped tube with a standard proximal dia–meter of 16 mm and a distal diameter of 10, 12, or 14.5 mm. It is available in different lengths of 7, 10, 12, and 14 cm. It is made of PTFE with an external nitinol stent, is very flexible, and therefore adapts easily to different configurations of the iliac artery anatomy (Figure 2). Another tubular stent-graft, the Passager, is less flexible and was used in the early part of this study. The Wallgraft is flexible and can adapt to different diameters of the vessel although it has the disadvantage of a short maximal available length. The Hemobahn is also a flexible stent-graft, but it is not funnel-shaped.

Figure 2. Radiograph of the abdomen. The Excluder stent-graft adapts well to the tortuous anatomy and to the varying diameters of the iliac artery.

Two different types of IAA were treated in this study, including true athero-sclerotic and anastomotic aneurysms. The smaller number of true aneu–

rysms in this study (35%) compared with the anastomotic aneurysms reflects, among other reasons, the often too short landing zone to seal and anchor the tubular device in true aneurysms. Of the 20 patients that were treated with open surgery, 15 had an insufficient proximal neck length (Table 1). An alternative for a tubular device in cases where this landing zone is too short is the aortouniiliac device with contralateral occluder and femorofemoral crossover bypass graft. In cases with a bilateral true IAA of the CIA with a short neck, the alternative can be an endovascular bifurcated device.
Most anastomotic IAA occur after a bifurcated graft with the distal anastomosis onto the CIA or EIA. The proximal sealing zone of the endograft can theoretically be chosen as long as the limb of the bifurcated graft in these cases. The limb diameters of the original bifurcation limbs in our series were 8 to 11 mm. The Excluder stent-graft, with a standard proximal diameter of 16 mm, adapted well to these smaller diameters and did not lead to any endoleaks or occlusions. The only occlusion in the series occurred in a Passager stent-graft that was positioned in a kinked CIA for a true aneurysm.
Special attention has to be drawn to patients with a bifurcated graft for occlusive disease. In these cases, an anastomotic IAA from an end-to-side anastomosis can still be in connection with the open native aortoiliac segment. A stent-graft from the bifurcation limb down to the iliac artery may, therefore, not be enough to exclude the aneurysm. The native iliac segment above the aneurysm may have to be coil embolized additionally, as in one of our patients (Figure 3).
Sacrifice of an IIA by over-stenting or coil embolization is unavoidable in most cases (70% in this study). This led to gluteal claudication in >10% of patients. Occlusion of the IIA could have been avoided in some cases by open repair with the distal anastomosis of the interposition graft on the iliac bifurcation. This would have resulted in higher mortality and morbidity rates, however.[1,4] A stent-graft with an incorporated iliac bifurcation for insertion of a covered stent-graft into the IIA is another promising solution for preserving flow to the IIA in future cases (Figure 4).
The choice between these different treatment modalities regarding the IIA has to be based on the individual patient’s situation.

Figure 3. A, Digital substraction angiography shows an aortic bifurcated graft for occlusive disease with an end-to-side anastomosis to the left external iliac artery. An Excluder contralateral limb (*long arrows*) was inserted to exclude an anastomotic aneurysm on the left side. The native aortoiliac system is patent (*short arrows*).

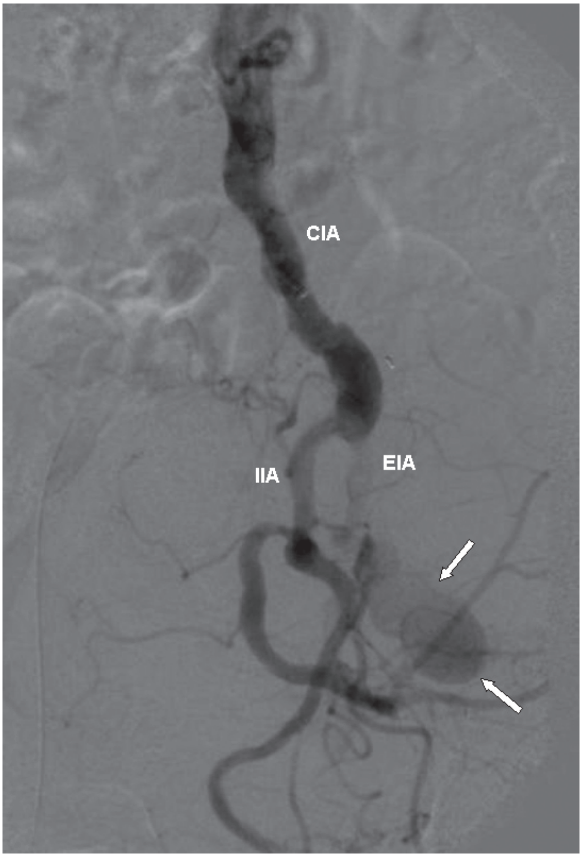

Figure 3. B, A selective angiogram of the left native aortoiliac system shows the common (*CIA*), internal (*IIA*), and external (*EIA*) iliac arteries, and the anastomotic aneurysm (*arrows*).

Results of this study are good, especially if one takes into account that emergent cases, which are associated with a substantial mortality after open surgery, were also treated. The complication rate was low, with a low incidence of migration, endoleak, and no cases of aneurysm rupture. This series, however, consists of a cohort of selected patients where anatomical criteria were used to make the selection, including the proximal neck, distal landing zone, and tortuosity in combination with factors as age and patient's choice. In addition, the knowledge that an IIA could be spared by performing an open reconstruction with the distal anstomosis on the iliac bifurcation, but would be sacrificed by endovascular repair, was a reason to perform open surgery, especially in bilateral cases.

Figure 3. C, A selective angiogram of the left native aortoiliac system after coil embolization of the EIA shows that flow through the CIA and IIA is preserved.

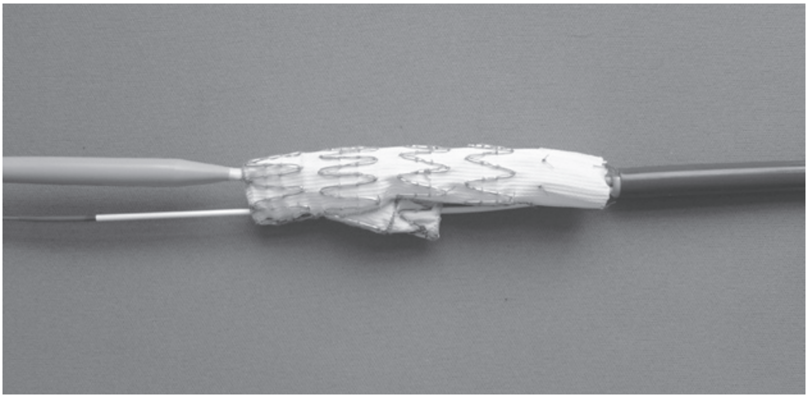

Figure 4. Iliac stent-graft with incorporated bifurcation. Introducer sheath and indwelling catheter are visible.

Conclusion

Endovascular repair of iliac artery aneurysms with flexible stent-grafts was proved to be a minimally invasive technique with low mortality and morbidity. In addition, the mid-term results suggest durability of the technique. It should therefore be regarded as a first choice treatment option for suitable aneurysms.

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Chapter 4

THE ROLE OF BRANCHED ENDOGRAFTS IN PRESERVING INTERNAL ILIAC ARTERIES

Ignace F. Tielliu, Wendy T. Bos, Clark J. Zeebregts, Ted R. Prins,
Jan J. van den Dungen, Eric L. Verhoeven

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Introduction

Intentional sacrifice of one or both internal iliac arteries (IIA) during aortoiliac aneurysm repair may lead to a wide variety of symptoms, including incapacitating hip and buttock claudication, colonic ischemia, erectile dysfunction, perineal or spinal ischemia, and buttock necrosis.[1] Buttock claudication, which is most prevalent, can occur after both bilateral and unilateral IIA sacrifice and has been reported in up to 45% of the cases.[2] The decision to sacrifice or preserve one or both IIA in the treatment of aortoiliac aneurysms is, therefore, important. The collateral circulation depends on the quality of the contralateral IIA and ipsi- and contralateral deep femoral collateral branches that all add to the vascularization of the pelvis.[3] Obviously, the level of activity of the patient should also be taken into account before attempting to preserve an IIA.

The standard endovascular technique to repair aortoiliac aneurysms where one cannot seal on the common iliac artery (CIA) is embolization of the IIA and extension of the graft into the external iliac artery (EIA). Nevertheless, several techniques have been described to preserve the IIA during endovascular repair, including the bell-bottom technique[4], the hypogastric artery bypass[5-8], the external-to-internal iliac artery stent-graft in combination with a crossover bypass graft[9-11], and surgical relocation of the iliac artery bifurcation.[12] A totally endovascular approach with an iliac branched device (IBD) has been available for a number of years, but only a few reports have been published so far.[13-20]

The consequence of intentional IIA occlusion on an individual basis is difficult to predict. On one side, even bilateral IIA occlusion has been reported with limited morbidity[21], but on the other side, persistent invalidating buttock claudication can occur even after unilateral occlusion of the IIA.[22] A totally endovascular repair with preservation of the IIA is, therefore, an appealing solution in selected cases. We report our treatment paradigm for the treatment of aortoiliac and isolated iliac aneurysms and initial results with the IBD.

Patients and methods

Patient selection

From September 2004 on, all patients presenting to our institution with an aortoiliac or isolated CIA aneurysm with a proximal neck suitable for endovascular repair were evaluated for treatment with an IBD. Level of activity of the patient was taken into account. An exclusion criterion to qualify for an IBD if the contralateral IIA was patent existed when the patient was not able to walk at least one block (e.g. due to cardiopulmonary restrictions). In the scenario of a risk to lose the only patent IIA, level of activity of the patient was not a reason for exclusion. Further selection for treatment with an IBD was done based on anatomical criteria specific to the technique. Absolute contraindications included an aneurysmal or heavily stenotic IIA, and a residual lumen (i.e. without thrombus) of the CIA <1.8 cm. Relative contra–indications included a sharp aortic bifurcation and pronounced tortuosity of the iliac vessels. Other anatomic selection criteria were not different from those used for standard endovascular repair of aortoiliac aneurysms. Informed consent was obtained from all patients.

Description of device and endovascular procedure

The IBD used in this series is derived from the Cook Zenith TFLE leg extension (William Cook Europe, Bjaeverskov, Denmark) (Figure 1). A side branch is attached to the leg in a 30° angle. The proximal diameter of the device is 12 mm. The diameter of the side branch is 8 mm.

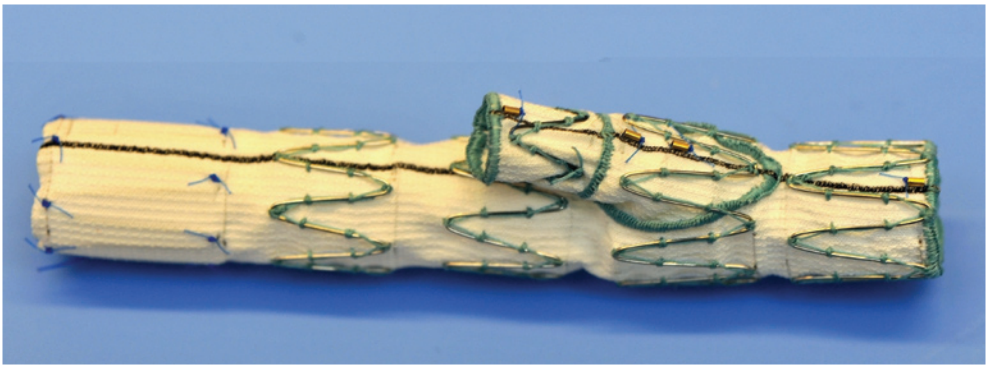

Figure 1. Iliac branched device with straight side branch (Cook).

For the distal diameter of the device, one can opt for 10 or 12 mm. An indwelling catheter passes through the internal iliac branch. All aortic stent-graft components used in conjunction with the IBD were Zenith TriFab devices (William Cook Europe). Technical details of the endovascular procedure with the use of this type of IBD have been described in recent reports.[13,16,17]
In our center and in most of the patients, a modified technique for aorto–iliac aneurysm repair with an IBD was used and this is described in detail in chapter 5.[20] Specific steps in this modified technique include the use of tromboned sheaths to enhance crossover sheath stability and avoid friction and entanglement of two guidewires in one sheath.
Because of the complexity and length of the procedure, regional or general anesthesia was preferred over local anesthesia, which is otherwise the standard for endovascular aneurysm repair in our center.[23] Access to the common femoral artery was performed by surgical cut down.
Technical success was defined as exclusion of the aneurysm with preservation of flow to the ipsilateral IIA.

Follow-up

Only patients treated and followed in our center were included for follow-up analysis. Plain radiography of the abdomen in four directions was performed before discharge. Patients were followed up with computed tomography (CT) scanning angiography at 6 weeks and 1 year postoperatively. Thereafter, they were seen on the outpatient clinic yearly with CT scan or duplex ultrasound scanning and plain radiographs of the abdomen, with special attention to occlusion, endoleak, and disconnection (Figure 2).
Antiplatelet therapy was started postoperatively and all patients were put on a daily regimen of 80 mg acetylsalicylic acid. In addition, clopidogrel 75 mg per day was administered for 6 weeks.

Statistical analysis

Data for continuous variables were expressed as mean ± standard deviation. Means were compared with Student's t test (normal distribution) or Mann Whitney U test (skewed distribution). Significance was set at $P < 0.05$. Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS) version 14.0 software (SPSS, Chicago, Ill, USA).

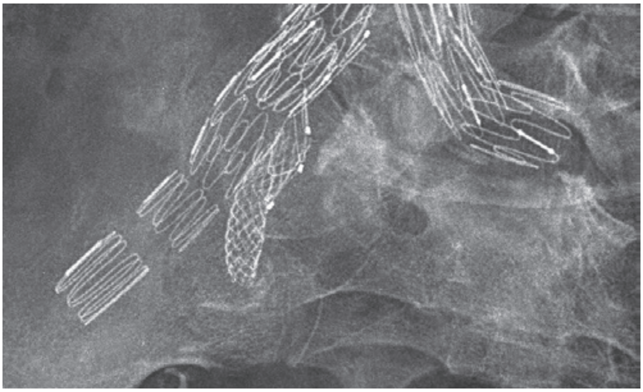

Figure 2. Detail of plain radiograph of the abdomen in left anterior oblique projection shows iliac branched device on the right side with stent-graft bridging the side arm with the internal iliac artery.

Results

Patient selection

During the study period, 59 patients were evaluated for treatment. Thirty-nine presented with an aortoiliac aneurysm with unilateral (n = 33) or bilateral (n = 6) CIA aneurysms. Twenty patients had unilateral (n = 15) or bilateral (n = 5) isolated true aneurysms of the CIA.

Seven patients were excluded from further evaluation because they had unilateral iliac disease and a limited level of activity (i.e. walking less than one block). Twenty-five patients, including six patients with bilateral disease, were refused for IBD because of anatomical reasons including aneurysmal IIA (n = 12), stenotic IIA (n = 7), severe tortuosity of the iliac vessels (n = 4), and small residual lumen of the CIA (n = 2).

The remaining 27 patients were treated with an IBD, including 20 patients with an aortoiliac aneurysm and seven patients with an isolated true CIA aneurysm. Five aortoiliac aneurysm patients had bilateral aneurysms, of which three were treated with an IBD on both sides. In total 30 IBDs were used in 27 patients. Anatomical application rate for IBD in this series was therefore 52% (27/52 anatomically evaluated patients). Mean age of these 27 patients was 70.4 ± 5.5 years (range, 58 to 79 years). Twenty-six patients were male.

Procedural details

General anesthesia was used in 18 patients (67%). Regional and local anesthesia was used in five and four patients, respectively. Insertion of the bridging stent-graft between branch and IIA was achieved via crossover technique in 25 patients. In the remaining two patients, an axillary artery approach was elected. Both patients had a CIA aneurysm after previous open aortobiiliac bypass graft.
Two types of bridging stent-grafts were used. An Advanta V12 covered stent (Atrium Medical Corporation, Hudson, N.H., USA) was used in 23 patients and a Jostent (Jostent stent-graft Peripheral, Abbott Vascular Instruments, Rangendingen, Germany) in three patients. In one patient, no bridging stent-graft was used.
For aortoiliac aneurysm cases with unilateral IBD implantation via standard crossover technique (n = 17), the mean operating time for the entire procedure was 185 ± 31 min, and the amount of blood loss and contrast medium used was 436 ± 273 cc and 231 ± 85 cc, respectively. Mean hospital stay for the whole study group (n = 27) was 3 days (range, 2 to 5 days), including the preoperative admission day.

Procedural complications and technical success

In one (3.7%) patient the procedure was not successful. After insertion of the IBD and achieving the crossover access, it proved impossible to catheterize the IIA due to heavy calcification and/or dissection of the orifice. The IIA was accidentally catheterized from the ipsilateral side while inserting an additional wire from the femoral artery. This access was used for coil embolization of the IIA and the side branch was covered with a limb extension.
In one patient a rupture of the EIA occurred during final ballooning of the inserted graft components. The rupture was immediately treated by endovascular means with an Atrium 9x59 mm covered stent.

Surgical complications and follow-up

There was no surgical mortality. Only one patient experienced a complication. He was readmitted with a pulmonary infection two days after discharge but left the hospital 7 days later after antibiotic treatment.

Follow-up was available for all 21 patients with 24 IBDs who were treated and followed in our hospital. Mean follow-up for these patients was 16.0 ± 14.0 months (range, 1 to 38 months). Occlusion of an IIA side branch occurred in three patients (3/24 side branches, 12.5%). One of these three patients developed buttock claudication whereas the other two remained symptom free. The patient in whom the procedure was technically not successful did not develop buttock claudication. In this patient, a control CT scan at 6 weeks demonstrated an excluded aortoiliac aneurysm with a patent contralateral IIA. One patient was diagnosed with an endoleak in the CIA aneurysm on the 6-weeks CT scan. On the 6-months duplex, no endoleak was diagnosed and there was no growth of the aneurysm. The patient is scheduled for a CT scan at 1 year. No EIA occlusions or device component separations were noted. Three patients died during follow-up as a result of urosepsis, pancreatitis, and lung carcinoma after 4, 6, and 7 months, respectively.

Discussion

Feasibility of iliac branched stent-grafting to preserve the IIA in aortoiliac or isolated CIA aneurysms has been demonstrated. In this series, the application rate was 27/59 (46%) with all patients included. One has to consider, however, that patients were only evaluated if they were at risk of losing both IIA or a single patent IIA. In case they were to lose only one of two patent IIA, IBD was only considered in physically active patients. Therefore, the anatomical application rate was rather 52% (27/52 patients).

The procedure was not successful in one patient. In this particular case the catheterization of the IIA proved impossible. At that moment, the IBD and the crossover sheath were already positioned. Fortunately, but accidentally, catheterization of the IIA from the ipsilateral femoral artery occurred, which enabled the embolization of the IIA. Obviously the branch of the IBD required covering with a bridging stent-graft to avoid a type III endoleak. In a later case, where we expected difficult catheterization of the IIA, we first positioned a wire from a crossover approach in the IIA, in order to guide the access and if necessary to balloon, or even stent, the orifice of the IIA.

Only four reports described a technique using the same type of IBD (derived from the Zenith TFLE leg extension and with a straight branch) (Table 1). Technical success in these series ranged from 85% to 100%. Occlusion of the IIA branch reached up to 24%. Two other reports described a different type of device with a side branch describing a 150° helical path around the external portion of the graft. Haulon et al. reported on 53 IBD inserted in 52 patients in a multicenter setting.[15] That report is an update from an earlier report by Greenberg et al.[14] Technical success rate was 94%. Early occlusions of the stent-graft in the IIA occurred in nine of the 52 cases (17%), including three intraoperative occlusions. No late branch occlusions (>30 days) were reported. EIA occlusion on the side of the IBD occurred in one case. No disconnection was observed in that series.

Table 1 Overview of studies reporting on the use of iliac branched devices (Zenith device with straight branch).

Author, year	Patients (IBD)	Technical success	Occlusion		Disconnection	Follow-up period (months) (range)
			IIA branch	EIA		
Serracino-Inglott,[17] 2007	8 (9)	9 (100%)	1 (11%)	NA	NA	6 (1-14)
Ziegler,[16] 2007	20 (20)	17 (85%)	2 (10%)	NA	NA	NA
Dias,[18] 2008*	17 (18)	17 (94%)	4 (24%)	1 (6%)	1 (6%)	20 (8-31)
Naik,[19] 2008	2 (2)	2 (100%)	0	0	0	10
This study, 2009	21 (24)	23 (96%)	3 (12.5%)	0	0	16 (1-38)

NA, data not available;
* update of earlier report.[13]

Besides the evaluation of the risk of pelvic ischemia and the decision to preserve an IIA (based on the physical activity level of the patient), the anatomy of the aortoiliac aneurysm is important in order to select suitable patients. Absolute contraindications for the technique include aneurysmal or heavily stenotic IIA and small lumen of the CIA. An aneurysmal IIA prevents adequate sealing. In our opinion, IIA larger than 10-12 mm should not be treated with this technique, unless one is prepared to advance the bridging stent-graft into a main tributary of the IIA after coil embolization of the branches arising from the aneurysmal portion. A small residual lumen of the CIA will prevent full opening of the side branch of the IBD and catheterization of the IIA. Mural thrombus increases the risk of embolic complications in these cases. Finally, it is doubtful whether one should attempt to preserve an atherosclerotic IIA.

The crossover technique needed to insert the bridging stent-graft between the branch of the IBD and the IIA becomes difficult in case of a sharp bifurcation and iliac artery tortuosity. In addition, if the CIA is shorter than

5 cm the IBD will stick out into the aorta and this will prevent the crossover technique. If one is prepared to come from the left axilla to insert the bridging stent-graft, all these contra-indications can be countered. In our series, approach from the left axilla was successful in two cases.

The decision to exclude patients with impaired activity level was based on the individual surgeon's assessment and not on clear guidelines. Although this is clearly a weakness of this and other studies concerning this subject, there is no literature available to guide us towards a stricter algorithm. It seems reasonable to try to preserve one IIA in most patients, but the decision to preserve both is open to discussion.

The decision to preserve an IIA must also include possible complications related to the technique. First, due to the 5-piece modular design, there is an increased risk of disconnection, especially at the level of the bridging stent-graft that connects the gate of the Zenith Tri-Fab and the IBD. To prevent this problem, a distal diameter of the bridging stent-graft of 16 mm is selected, which fits tightly in the 12 mm proximal diameter of the IBD. Maximal overlap should be sought for to add to the stability of the connection. Second, there is a higher risk of occlusion of the limb of the IBD that seals the EIA in tortuous or smaller EIA. Third, the technique adds a significant amount of time and resources to the whole procedure, compared to standard endovascular aneurysm repair (EVAR). The mean operating time of EVAR combined with a unilateral IBD and without additional procedures was 185 ± 31 min (n = 17) compared to 116 ± 30 min (n = 232) for standard EVAR with the Zenith device in our institution[24] ($P < 0.001$; Mann-Whitney U test). This comparison, how–ever, would only be valid if one includes the time needed for coil embolization of the affected IIA in a selected aortoiliac aneurysm group.

Conclusion

The IBD technique is a totally endovascular option to preserve the IIA in selected patients with aortoiliac or isolated CIA aneurysms. Technical success rate in our series was 96.3%. The technique adds to the complexity of the endovascular repair, is more expensive, but seems safe in the short term. Longer term results are awaited and further studies, especially trials randomizing anatomically suitable patients between EVAR with IBD and EVAR with blocking of the IIA, are needed to determine the true indication criteria for this technique.

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Chapter 5

A MODIFIED TECHNIQUE FOR ILIAC ARTERY BRANCHED ENDOGRAFTING USING A "TROMBONED" SHEATH

Ignace F. Tielliu, Clark J. Zeebregts, Jan J. van den Dungen,
Eric L. Verhoeven

Journal of Vascular Surgery 2008;48:1605-1608

Introduction

Iliac branched stent-grafting is an endovascular technique to preserve flow into one or both internal iliac arteries (IIA). The technique can be used in aortoiliac aneurysms in conjunction with the Zenith stent-graft (Cook Inc., Bloomington, Ind, USA) or in solitary iliac artery aneurysms that have an extension to the iliac bifurcation. Although the literature is not completely in agreement with regard to the risk of complications after intentional sacrifice of one or both IIA, it is clear that a number of patients will suffer from ischemic complications. The most common complication is buttock claudication, which can occur in up to 30% of the patients.[1] More severe ischemic events like colon or buttock necrosis, however, are rare.

This technique, using an iliac branched device (IBD), is the only totally endovascular option available to preserve flow in the IIA. Other techniques have been used such as surgical relocation of the IIA, or the external to internal iliac artery stent-graft with surgical crossover bypass. These procedures, however, are far more invasive compared to any endovascular procedure. Two types of IBD have been used and their respective results have been published.[2-7] One IBD consists of a 12 mm tubular stent-graft with a 6 or 8 mm helical side branch attached. The side branch is wrapped around the tubular graft in a 150° circumference.[4] The second IBD type is based on the Zenith TFLE leg extension (Cook Inc.), with a proximal diameter of 12 mm and a distal diameter of 10 or 12 mm. The straight side branch, 8 mm in diameter and 21 mm long, is attached to the tube in a 30° angle.[2,3,6,7] Both types of IBD seem to present with some minor advantages and disadvantages but they have not been compared up to now. They both involve the use of a preloaded indwelling wire that passes through the internal iliac branch. This indwelling wire can be advanced and snared from the contralateral side. This through-and-through crossover wire enables the advancement of a stent-graft from the contralateral side to bridge the gap between the iliac branch and the IIA. For the introduction of this bridging stent-graft, a stable position of the crossover sheath is mandatory. Therefore, it has been advised to keep the through-and-through indwelling wire in position until the bridging stent-graft is in place. This requires working with parallel wires through one sheath, and can cause problems due to friction and entangling.

To solve this problem, we developed a modified technique which allows working in a co-axial way at all times, with a lower risk of intra-operative technical complications. For completeness, we report that the technique was applied in IBD with the straight side branch only.

Technique

The technique requires standard bilateral femoral artery access. Introduction of the 20F IBD is achieved through the ipsilateral femoral artery. The indwelling wire is snared from the contralateral femoral artery, to achieve a through-and-through crossover access. After angiography, the body and side branch of the IBD are deployed, but the ipsilateral limb of the IBD is kept constrained inside the sheath (Figure 1). This allows for later repositioning if needed. A 40 cm 10F flexor crossover guiding sheath (Balkin, William Cook Europe, Bjaeverskov, Denmark) is introduced over the aortic bifurcation and into the body of the IBD. Then a 55 cm 7F flexor guiding sheath (ANL 1, William Cook Europe) is advanced through the 10F sheath into the iliac side branch of the IBD. This “trombone” technique results in a stable position to work with. The indwelling through-and-through wire can now be removed (Figure 2). This manoeuvre will result in the iliac branch limb opening up, thus facilitating catheterization of the IIA. After catheterization of the IIA, a stiffer wire (Amplatz super stiff, Cook Inc.) is inserted and the ANL 1 guiding sheath advanced inside the IIA. In order to reduce the gap between the side branch and the orifice of the IIA, the IBD can be retracted over the two rails formed by the ANL 1 and the main introduction device (Figure 3).

To conclude the procedure, the ipsilateral limb of the IBD is deployed and the bridging stent-graft introduced (Figures 4 and 5). Deploying the bridging stent-graft will cross the gap between the side branch and the ostium of the IIA.

Since the introduction of this modified technique, 13 patients with a mean age of 65.3 years have received 14 IBD for treatment of solitary iliac artery aneurysms (n = 3) or aortoiliac aneurysms (n = 11). Initial technical success was 100% with complete exclusion of the aneurysm and an open IIA at the end of the procedure.

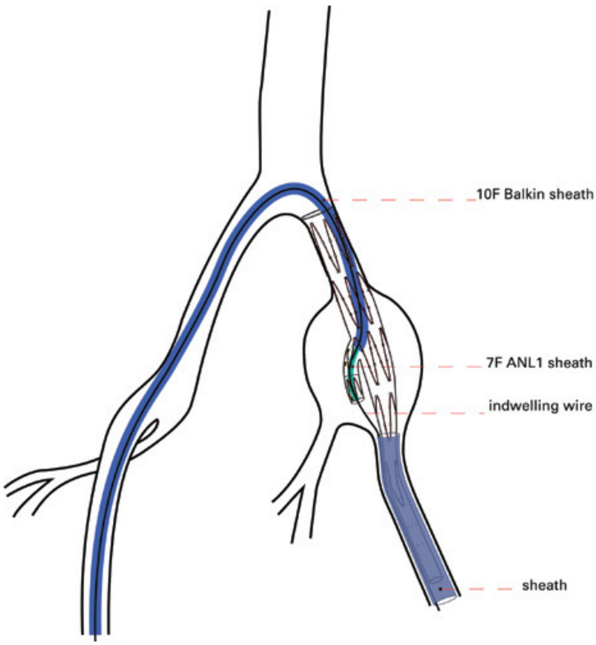

Figure 1. Body and side branch of iliac branched device deployed. The ANL sheath is introduced inside the Balkin sheath (crossover "trombone" technique).

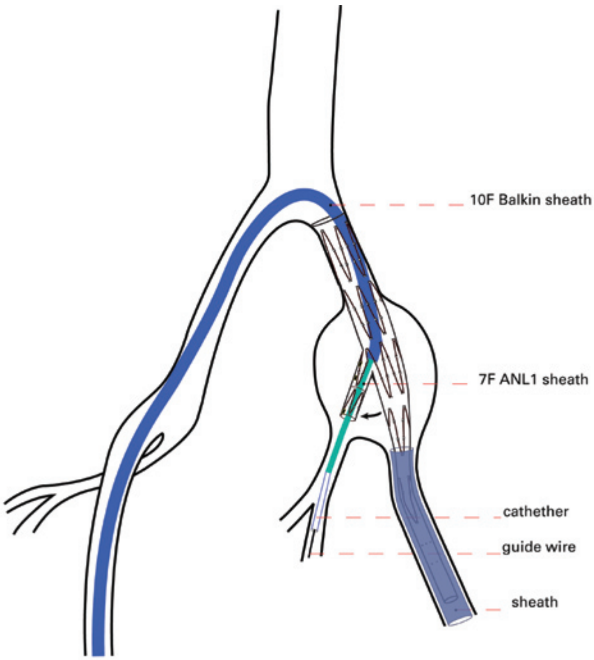

Figure 2. Indwelling wire removed. This opens up the iliac branch limb (*black arrow*). The ANL 1 sheath is advanced inside the internal iliac artery.

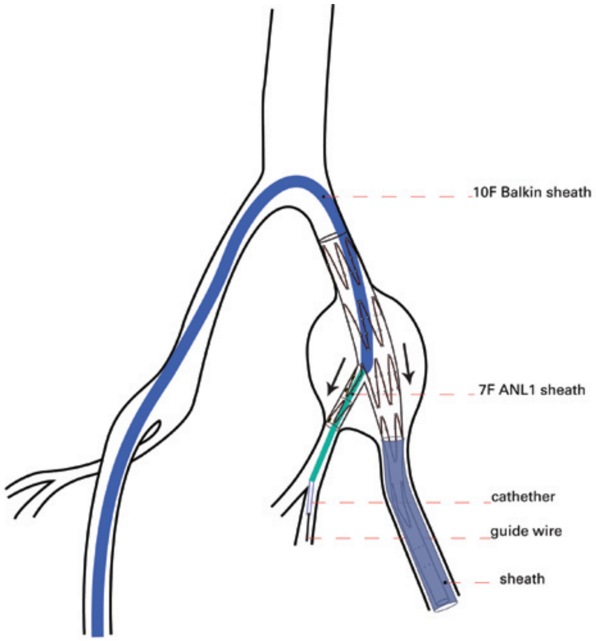

Figure 3. A, Iliac branched device retracted (black arrows) over two rails (the ANL sheath and the main introduction device).

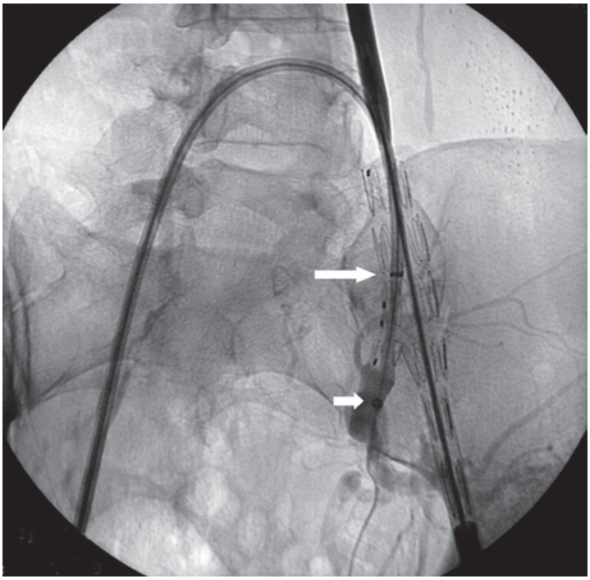

Figure 3. B, Intraoperative angiogram shows the situation as in Figure 3 A with partially deployed iliac branched device (proximal part and branch), crossover 10F Balkin sheath (long arrow) with 7F ANL sheath inside (short arrow). Guide wire inside the internal iliac artery. The external part of the device is still constrained in the sheath.

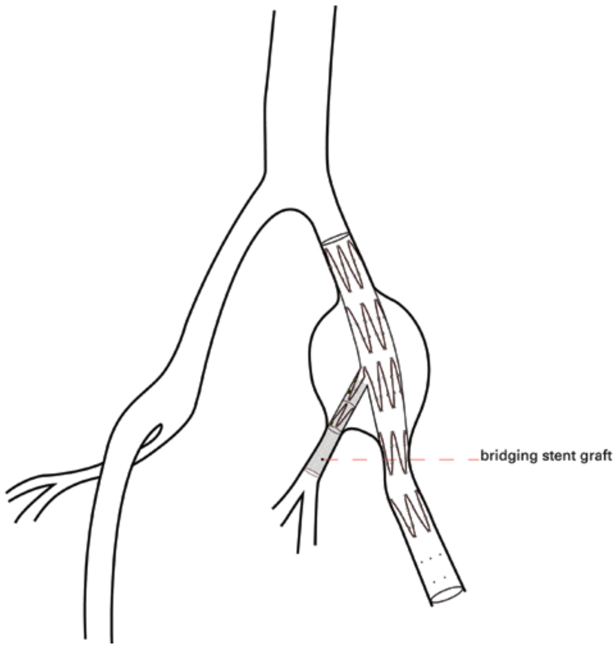

Figure 4. Ipsilateral limb of the iliac branched device deployed and the bridging stent-graft introduced and deployed.

Figure 5. Completion angiogram shows unrestricted flow to the internal iliac artery.

Discussion

This report describes the use of a “trombone” technique which allows for early removal of the indwelling wire. It was devised as an easier and safer technique to get a bridging stent-graft from the contralateral femoral side into the IIA, as compared to the technique that was published so far in several reports.
The indwelling wire is an integral part of the IBD and runs outside the external iliac part, through the iliac side branch and inside the common iliac part of the device. This indwelling wire is snared from the contralateral side and thus becomes a through-and-through wire. The use of the “trombone” technique should provide a stable position of the crossover sheaths as discussed. The advantages following the removal of the indwelling wire are threefold. First, the iliac limb will naturally open up and face the orifice of the IIA. Second, the IBD can be retracted carefully over the two rails which will reduce the gap and stabilize the position of the IBD. Third, in this way a much shorter bridging stent-graft can be chosen. Indeed, about 1.5-2 cm overlap and the same length inside the IIA will suffice with the graft in such a stable position. This should avoid kinking of the balloon expandable and fairly stiff bridging stent-graft and occlusion of the IIA.
Only a few reports on the use of the IBD have been published so far.[2-7] In these reports, a different technique is described for the insertion of the bridging stent-graft. The guiding sheath is only advanced up to the level of the side branch. With the purpose to keep the crossover sheath in position, the indwelling wire is kept in place and a second guide wire is used alongside the first one for catheterization of the IIA and introduction of the bridging stent-graft. Using this technique in earlier cases resulted in technical problems such as extreme difficulty to advance the bridging stent-graft inside the IIA, probably due to friction and/or entangling of the wires. Using more force did not help and several times even luxated the crossover sheath. In our early experience we also used far longer bridging stent-grafts to achieve a longer sealing zone in the IIA but this resulted in kinking and occlusion in three cases.

Conclusion

We have abandoned the standard technique for use of the IBD in favor of a modified technique which uses “tromboned” sheaths for stability and avoids the potential problems with the use of parallel wires inside one sheath. With maximal reduction of the gap by retraction of the IBD and selection of a shorter bridging stent-graft, one can achieve a stable position of the device and avoid kinking and risk of occlusion of the IIA.

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ADDENDUM TO CHAPTER 5

The following paragraphs include a discussion concerning Chapter 5[1] between Manning and Ivancev (Vascular Centre, Malmö University Hospital, Malmö, Sweden) and our group as published in

Letter to the editor. Journal of Vascular Surgery 2010;51:1326.

Manning and Ivancev wrote in a letter to the editor a comment to our report in the Journal of Vascular Surgery. The authors caution against adopting the technique with “tromboned” sheaths for two reasons.
First, reorientation of the side branch could be difficult if catheterization of the internal iliac artery origin proves difficult, especially with the 7F sheath inside the branch. In addition, in the event that the side branch is success–fully catheterized, pulling down the main device ‘over the rails’ of the 7F and 10F sheaths could risk kinking of the iliac branch when the sheaths are withdrawn, since the origin of the internal iliac artery is often quite posterior in the aneurysm sac, compared with the external iliac artery ostium.
Second, the authors believe that removal of the through-and-through wire prior to insertion of the bridging stent graft ignores its potential as a valuable stabilizing mechanism and also ignores its value as a safety mechanism to facilitate recatheterization of the internal iliac artery, should access to the iliac branch be lost during this manoeuvre. In their experience, the presence of a lax 0.018 inch through-and-through wire was not found to be a significant impediment to successful catheterization of the internal iliac artery, nor did they encounter significant problems with friction and entangling of guide wires.
Manning and Ivancev do not agree that the modification of the standard technique to one that involves passage of the larger 10F sheath across the aortic bifurcation and early withdrawal of the through-and-through wire, as we described, will make the procedure easier or safer.

Reply to letter to the editor by Tielliu, Zeebregts, Verhoeven, van den Dungen.
Journal of Vascular Surgery 2010;51:1327.

We would like to thank Manning and his colleagues for their thoughtful comments regarding our modified technique with the use of iliac branch devices (IBD). We also appreciate that they prefer the standard technique to our technique with “tromboned” sheaths.

The IBD we use features an 8 mm straight side branch. For the helical branch on the contrary, one can opt for a 6 or 8 mm diameter side branch. These two devices are different and we have used only the straight side branch device.
We did use 0.018 and 0.014 inch through-and-through wires, but had problems here and there. In one case where the bridging stent-graft could not be advanced, withdrawal of the through-and-through wire solved the problem. The combination of a 10F Balkin sheath (in the body of the IBD) and a 7F ANL 1 flexor sheath (through the side branch of the IBD) is very stable because of the stiffness of the Balkin sheath. With growing experience, the new 12F ANL 1 flexor sheath is now used instead of the Balkin sheath with equally good results. Reason for this change is the easiness to cross the aortic bifurcation with the flexor sheaths.
As mentioned, the side branch always opens up when withdrawing the through-and-through wire, which results in usually instant and easy catheterization of the internal iliac artery. Repositioning of the side branch is possible but rarely needed. Obviously, it is wise to orient the branch adequately before opening the main body to the level of the side branch. In this respect, a posteromedial orientation of the branch is usually recommended. Advancing the 7F sheath over a stiff wire provides all the extra stability needed and guarantees an easy insertion of the bridging stent-graft. Removal of the through-and-through wire also enables retraction of the device. This manoeuvre reduces the gap between the side branch and the internal iliac artery, which allows for selecting a shorter bridging stent-graft (38 mm instead of 59 mm), and it also stabilizes the whole IBD. It is mandatory to visualize the retraction process to avoid kinking of the side branch. This does not require angiography, as fluoroscopy will demonstrate the moment the side branch is bouncing against the ostium of the internal iliac artery.
In conclusion, in the IBD scenario we recognize the possibility of using the standard technique but are comfortable with the removal of the through-and-through wire. In contrast, for upper approaches in thoracoabdominal branched cases (and some IBD where one needs the upper approach) we prefer the 0.018 inch through-and-through wire. There are many ways to reach Rome, apparently.

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Section II

ENDOVASCULAR TREATMENT OF POPLITEAL ARTERY ANEURYSMS

Chapter 6

ENDOVASCULAR TREATMENT OF POPLITEAL ARTERY ANEURYSMS: RESULTS OF A PROSPECTIVE COHORT STUDY

Ignace F. Tielliu, Eric L. Verhoeven, Clark J. Zeebregts, Ted R. Prins,
Mark M. Span, Jan J. van den Dungen

Journal of Vascular Surgery 2005;41:561-567

Introduction

Popliteal artery aneurysms (PAA) account for most peripheral aneurysms. They are potentially dangerous, with a 5-year cumulative risk for complications ≤68%.[1] The most common complications are acute thrombosis, with occlusion of the aneurysm, and distal embolization. As a result, acute ischemia may occur and will lead to limb loss in ≤40% of patients.[2] In addition, chronic distal embolization of small mural thrombi can lead to progressive occlusion of tibial and peroneal arteries, resulting in chronic or acute limb ischemia.

To prevent these severe complications, elective treatment is advocated.[2-4] Whether small and asymptomatic aneurysms should be treated is still a point of debate.[5,6] Nevertheless, most authors consider a diameter cutoff point of 20 mm a criterion for treatment, and some treat even smaller aneurysms when mural thrombus is present.[1,4,6,7]

Open surgical treatment with a venous bypass graft is the treatment of choice for most surgeons. Patency rates of these reconstructions depend mainly on the quality of the peroneal and tibial arteries, the type of bypass material, and whether the reconstruction was performed for acute ischemia or in the elective setting.[2,3,8,9]

The first endovascular repair of a PAA, performed with a homemade device, was reported in 1994 by Marin.[10] Thereafter, several case reports and relatively small series have been published describing the endovascular treatment of PAA (Table 1).

Advantages of the endovascular treatment include the minimally invasive character of the procedure, with only a small incision in the groin, minimal morbidity, and a shorter operation time and hospital stay.[11] A particular problem associated with this technique is that the stent-graft crosses the knee joint. Repetitive stress on the device in this bending zone may lead to complications, including kinking, fracture of the stent-graft material, and occlusion.[11]

This study describes the results of the largest worldwide series of PAA treated with a single type of endovascular stent-graft and analyzes the predictive value of different variables on stent-graft occlusion.

Patients and methods

Between June 1998 and June 2004, all consecutive PAA referred to the University Medical Center Groningen that measured >20 mm in diameter on duplex ultrasound scanning were analyzed for endovascular treatment. Two types of aneurysms were included:

1. Aneurysms in patients who did not present with acute limb ischemia. In these patients, angiography was performed to determine anatomical suitability, including the presence of a landing zone in the proximal and distal popliteal artery of ≥3 cm in length, the absence of extensive aneurysmal or stenotic disease at the level of the iliac and femoral arteries, and the presence of at least one good tibial or peroneal artery serving as a run-off vessel.

Table 1. Literature overview of popliteal artery aneurysms treated with commercially available stent-grafts.*

Author, year	No. of aneurysms	Type of stent-graft (No. per type)	No. treated emergently for acute ischemia (%)	Follow-up period (months; mean)	Occlusions (No. per type) (%)
Marcadé,[13] 1996	6	CES	0	6	1
Kudelko,[14] 1998	1	WG	0	10	0
Bürger,[15] 1998	1	HB	1	6	0
Beregi,[16] 1999	3	CES	0	24	0
Müller-Hülsbeck,[17] 1999	6	CES(4); P(1); WS(1)	6 (100)	4	4 (3CES; 1P) (67)
Henry,[18] 2000	10	P(7); CORV(3)	-‡	-‡	5 (3CORV; 2P) (50)
Ihlberg,[19] 2000	1	HB	0	5	0
Howell,[20] 2002	13	WG	0	12	4
Gerasimidis,[21] 2003	9	HB(6); WG(2); P(1)	0	14	4 (3HB; 1WG) (44)
This study, 2005	57	HB; VB†	5 (9)	24	12 (21)

CES, Cragg Endopro system 1; *WG*, Wallgraft; *HB*, Hemobahn; *P*, Passager; *WS*, Wallstent; *CORV*, Corvita; *VB*, Viabahn.

* Reports on home-made devices were not included.

† In some patients both the Hemobahn and Viabahn stent-graft were used to treat the popliteal aneurysm according to the diameters and availability of according stent-grafts.

‡ Not stated in the article.

2. Some patients with aneurysms presented with acute limb ischemia. These patients with an acute occlusion of a PAA but with a viable limb (Rutherford category I and IIa acute limb ischemia)[12] were usually treated by thrombolysis. After successful recanalization, they were evaluated for endovascular repair as in an elective setting.

This study was approved by the institutional medical ethics committee, and each patient provided informed consent.

Endovascular procedure

On admission, duplex ultrasound scanning was performed to determine intima-to-intima diameters of landing zones and length of the aneurysm. In addition, the proximal and distal margins of the aneurysm were marked with a pencil on the patient's leg. In the presence of mural thrombus, this proved to be a reliable indication of the exact localization of the aneurysm.
All procedures were performed in an operating theatre by an endovascular team that included a vascular surgeon and a radiologist. Access to the ipsilateral common femoral artery was achieved by open dissection of the groin. A 30-cm long 12F sheath was introduced and continuously flushed with heparinized saline (500 IU/500 mL). Heparin (5,000 IU) was also administered intravenously. A calibrated straight angiocatheter was positioned just proximal to the trifurcation of the popliteal artery, after which angiography was performed by hand injection through the sheath.
The selection of the appropriate stent-graft was based upon measurements of landing zone diameters and lengths. Both preoperative duplex ultrasound scanning and intraoperative calibrated angiography were used in the decision-making. Self-expanding nitinol-supported stent-grafts with an inner lining of ultrathin expanded polytetrafluoroethylene (PTFE) were used. Up to June 2003, only the Hemobahn stent-graft (W.L. Gore & Associates, Flagstaff, Ariz, USA) was used (Figure 1). After June 2003, the Viabahn stent-graft (W.L. Gore) also became available and was used instead of the Hemobahn for the available diameters of 6, 7, and 8 mm. Technical improvements of the Viabahn included the deployment over a 0.035-inch instead of a 0.025-inch guidewire, concentric deployment instead of unfolding, and deployment starting at the distal end instead of the proximal end in the Hemobahn, providing an easier and more accurate deployment distally.

Follow-up

In an effort to avoid kinking of the stent-graft, our patients were advised to avoid >90° knee flexion. Ankle brachial pressure index (ABI), duplex ultrasound scanning, and plain radiographs of the knee were made at discharge, after 6 weeks, and every 6 months thereafter. Radiographs of the knee were made in extension, including both anteroposterior and lateral views, and in 90° flexion. All patients received antiplatelet or anticoagulation therapy. Up to April 2003, antiplatelet therapy consisted of 80 mg/day acetylsalicylic acid (ASA). After April 2003, this protocol was changed and 75 mg clopidogrel was added for 6 weeks after the operation. Patients who were taking anticoagulants before the intervention, mostly for cardiac indications, continued this therapy after the operation. These patients were also given clopidogrel for 6 weeks.

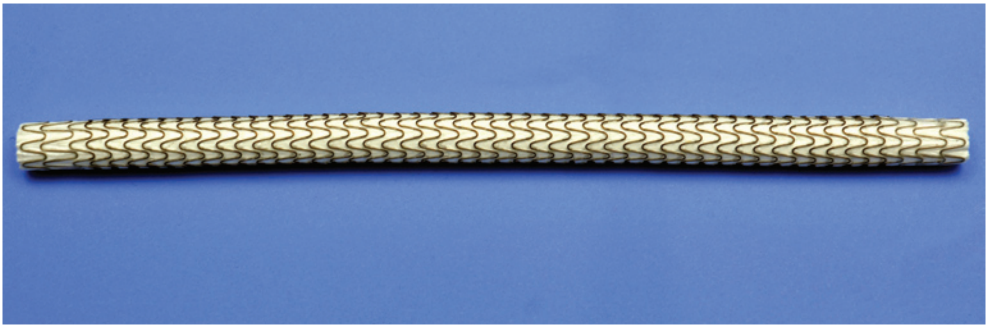

Figure 1. Viabahn stent-graft (W.L. Gore)

Definitions

Quality of arterial outflow was assessed on a preoperative angiogram and reported by the number of peroneal and tibial arteries that were patent up to the level of the ankle. The *total stented length* was defined as the total length of the popliteal artery covered by the stent-graft, measured on plain radiograph of the knee. This equals the sum of the length of the stent-grafts used, minus the sum of the length of the overlap zones. The available stent-graft lengths were 5, 10, and 15 cm; therefore, more than one stent-graft was needed in some cases. The *overlap zone* was defined as the extent of insertion of one stent-graft into the other. The *landing zone* was defined as the site of healthy popliteal artery where the stent-grafts ended proximally and distally to the PAA. A procedure was *technically successful* when the PAA was excluded with preservation of the outflow vessels.

Statistical analysis

Data for continuous variables were expressed as mean ± standard deviation. Data were prospectively collected and analyzed in a retrospective manner. Primary outcome measures were graft patency, limb survival, and patient survival. Time-to-event variables were studied with Kaplan-Meier survival analysis using the Statistical Package for the Social Sciences (SPSS) version 11.0 software (SPSS, Chicago, Ill, USA). The predictive value of the different variables on occlusion of the stent-graft was assessed in univariate analyses. Categorical variables were analyzed with the Chi square test and continuous variables were analyzed with the Student t test (normal distribution) or Mann-Whitney U test (skewed distribution). Significant factors of the univariate analyses were entered in a logistic regression model. $P < 0.05$ was considered statistically significant.

Table 2. Details of patients excluded for endovascular repair.

Exclusion criteria	n	Treatment
Elective cases		
Inflow disease	2	Below-knee bypass
Outflow disease*	3	Below-knee bypass
Combination of in/outflow disease	1	Below-knee bypass
Thrombosis of the aneurysm	2	No treatment
Acute cases		
Thrombosis of the aneurysm	2	Below-knee bypass (1) / No treatment‡ (1)
Total	**10**	

* One patient had a high anterior tibial artery origin; two patients had a too short distal landing zone.

† Thrombosis diagnosed on day of planned endovascular treatment; no treatment because asymptomatic.

‡ Patient presented with marginally threatened acute limb ischemia (Rutherford category II.a)[12] with evolution to moderate claudication in a few days time. He was not treated because of extensive comorbidity, including impaired renal function.

Results

A total of 67 PAA in 57 patients were evaluated for endovascular repair. Ten PAA were excluded from endovascular repair by the selection criteria (Table 2). The remaining 57 PAA (85%) in 48 patients were treated endovascularly. The mean age of these patients was 66 ± 9 years (range, 52 to 85 years), and 91% were men. Twelve (21%) of the 57 PAA were symptomatic and presented with acute ischemia (n = 5), venous compression (n = 3), claudication (n = 2), pain in the popliteal fossa (n = 1), or rupture (n = 1). Six patients were treated in an acute setting of whom five presented with acute limb ischemia. They were treated with thrombolytic therapy (urokinase) and subsequent stent-grafting. The other patient had a ruptured aneurysm. The mean PAA diameter was 29 ± 8 mm (range, 16 to 65 mm). Two smaller aneurysms (16 and 18 mm) occurred in two of the patients who presented with acute limb ischemia. All repairs were technically successful. Details of the operative procedures are listed in Table 3.

Table 3. Details of operative procedures.

	n	%
Preoperative		
Grade of outflow quality (number of infrapopliteal vessels)		
1	4	7
2	14	25
3	39	68
Thrombolytic therapy	5	9
Intraoperative		
Approach		
EIA*	1	2
CFA	56	98
No. of stent-grafts per aneurysm		
1	18	32
2	32	56
3	6	10
4	1	2
Patients treated bilaterally in one session	6	10
Ancillary procedures		
Aortic bifurcation graft	1	
Interposition graft CFA	5	
PTA SFA	1	
Total	7	12
Postoperative		
Antiplatelet therapy with/without clopidogrel	17/33	
Anticoagulation with/without clopidogrel	1/6	
Antiplatelet therapy or anticoagulation with/without clopidogrel	18/39	46

CFA, common femoral artery; *EIA*, external iliac artery; *SFA*, superficial femoral artery; *PTA*, percutaneous transluminal angioplasty; ASA, acetylsalicylic acid.
* Treated with an aortobiiliac bypass graft for abdominal aortic aneurysm in the same session.

During a mean follow-up of 24 months (range, 1 to 72 months), 12 stent-grafts occluded (21%). Thrombolytic therapy was used to recanalize these occluded vessels in seven patients, open thrombectomy was performed in one patient, and the other four patients were managed conservatively

(Table 4). Thrombolytic therapy failed in two out of the seven patients, and additional thrombectomy was then performed. No patient required amputation or bypass surgery.

Table 4. Details of 12 occlusions.

Patient Number	Age (y)	Time to occlusion (months)	Symptoms* (Rutherford)[12]	Treatment	Re-occlusion	Treatment	Residual symptoms* (Rutherford)[12]	Status	Follow-up (months)
1	82	6	Claudication (2)	-	-	-	Claudication (1)	Occluded	65
2	82	6	Acute ischemia (IIb)	-†	-	-	Claudication (2)	Occluded	56
3	72	6	Acute ischemia (IIa)	Thrombectomy	Yes	No	Asymptomatic (3)	Occluded	51
4	78	1	Acute ischemia (IIa)	Thrombolysis‡	Yes	No	Claudication (3)	Occluded	45
5	55	9	Claudication (2)	-	-	-	Claudication (2)	Occluded	45
6	59	1	Acute ischemia (IIa)	Thrombolysis§	No	-	Asymptomatic (0)	Open	41
7	68	28	Claudication (2)	-	-	-	Claudication (2)	Occluded	55
8	53	1	Acute ischemia (IIa)	Thrombolysis	Yes	No	Claudication (3)	Occluded	24
9	75	1	Acute ischemia (IIa)	Thrombolysis	No	-	Asymptomatic (0)	Open	20
10	66	23	Claudication (3)	Thrombolysis	Yes	Thrombectomy	Claudication (1)	Open	40
11	61	10	Claudication (3)	Thrombolysis**	No	-	Claudication (1)	Open	20
12	63	1	Acute ischemia (IIa)	Thrombolysis††	Yes	No	Claudication (3)	Occluded	2

* Rutherford classification for acute limb ischemia (I, IIa, IIb, and III) and for chronic limb ischemia (0 to 6).

† Occlusion of Hemobahn following occlusion of iliac inflow tract (Vanguard contralateral limb), treated with crossover bypass to the deep femoral artery without additional treatment to recanalize the occluded Hemobahn.

‡ Thrombolysis followed by iliac artery and superficial femoral artery PTA and stent.

§ Thrombolysis followed by Wallstent to cover a fold in the proximal end of the Hemobahn.

** Thrombolysis failed and was followed by open thrombectomy and proximal and distal patch plasty.

†† Thrombolysis followed by stent at the proximal border of the stent for stenosis.

Primary and secondary patency rates were 80% and 90% at 1 year, and 77% and 87% at 2 years follow-up, respectively (Figure 2). None of the stent-grafts occluded in the emergent group.

At univariate analysis, treatment with clopidogrel was the only significant predictor for success (n = 18, patency 100%) (P = 0.008). Age of the patient, diameter of the aneurysm, type of stent-graft, number and length of endoprostheses, length of overlap zone, number of run-off vessels (one vs two or three), and type of surgery (elective vs emergent), were not.

In a multivariate logistic regression, the effect of clopidogrel intake was again found to be the only significant predictor for success ($x^2[1] = 10.526$, $P < 0.01$).

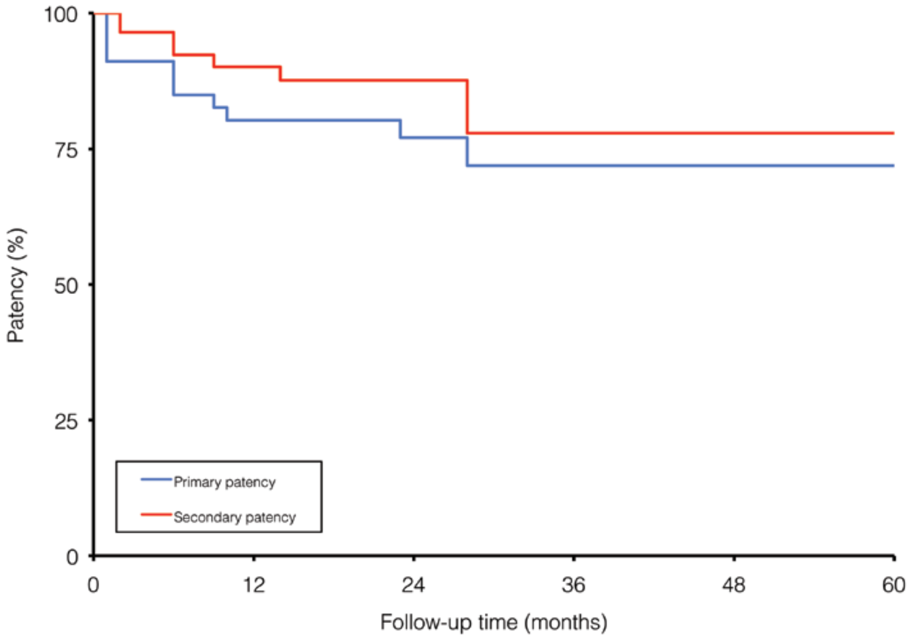

Figure 2.

Kaplan-Meier estimated cumulative primary patency rates.

Time (months)	12	24	36	48	60
Cumulative proportion (%)	80.3	77.1	71.9	71.9	71.9
Number at risk	33	21	10	7	3
Standard Error	<0.1	<0.1	<0.1	<0.1	<0.1

Kaplan-Meier estimated secondary patency rates.

Time (months)	12	24	36	48	60
Cumulative proportion (%)	90.1	87.6	77.9	77.9	77.9
Number at risk	38	24	11	7	3
Standard Error	<0.1	<0.1	<0.1	<0.1	<0.1

Other complications occurred, including migration of the prosthesis, stenosis at the border of the stent-graft, continuous sac enlargement, and breakage of the stent material (Table 5). Early migration led to the disconnection of two overlapping stent-grafts and a type III endoleak in one patient. Diagnosis was made on the first postoperative day with radiograph, and repair with a bridging stent-graft was successful (Figure 3). In two other patients, the sealing zone initially chosen was short, and a slight late migration, which led to a type I endoleak, occurred. Repair with an extension was successful. Stenosis at the border of the stent-graft occurred in two patients.

Table 5. Complications other than occlusions.

Complication	n	Treatment	Status
Migration			
Without endoleak	5	-	Patent
With type I endoleak	2	Extension	Patent
With type III endoleak*	1	Bridging stent-graft	Patent
Sac enlargement	1	-	Patent
Stenosis†	2	PTA	Patent
Stent breakage	2	Thrombectomy‡ (1); No treatment§ (1)	Patent‡; Occlusion§
Total	**13 in 9 patients**		

PTA, percutaneous transluminal angioplasty.

* Type III endoleak was diagnosed on the duplex scan on the first postoperative day; radiograph showed disconnection.

† One of these two patients had an extension proximally and a PTA distally, and is the patient with the sac enlargement.

‡ This patient had an occlusion (patient 11; Table 4).

§ This patient had an occlusion (patient 7; Table 4); no treatment because of only mild claudication.

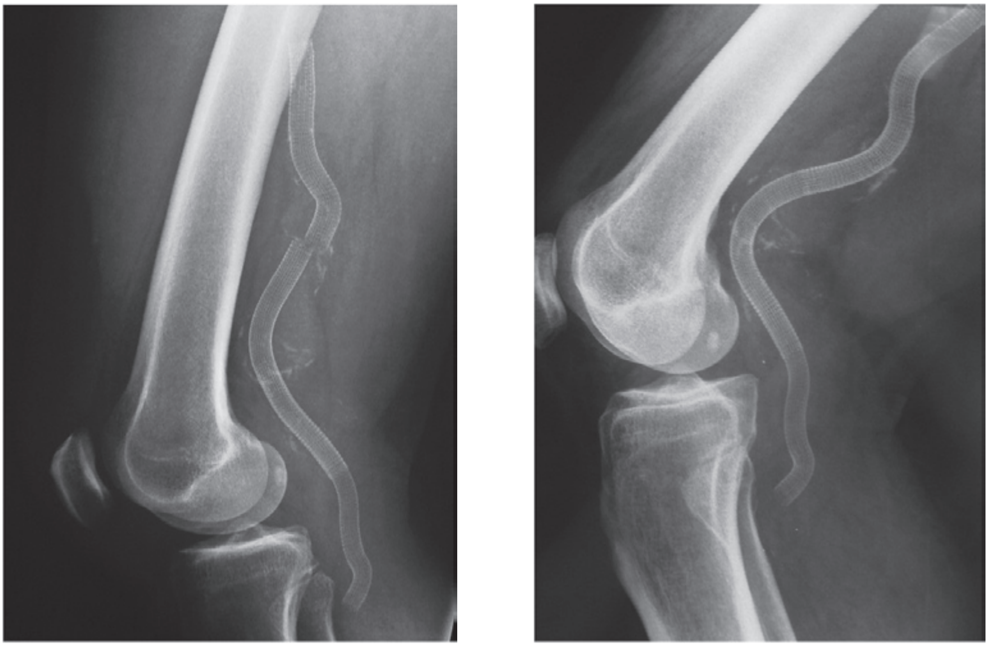

Figure 3. Radiograph of the knee in lateral projection shows disconnection between two overlapping stent-grafts before (left) and after (right) correction with a bridging stent-graft.

One of these patients presented with claudication after 12 months and was successfully treated with percutaneous transluminal angioplasty (PTA). The other patient was asymptomatic but the distal stenosis was diagnosed on angiography during repair for a proximal endoleak. Treatment with PTA was successful. Breakage of the stent material was observed in two patients, which led to occlusion in both cases.

During follow-up, five patients died of unrelated causes after a mean of 40 ± 20 months after the procedure. The 1-year and 2-year patient survival was 100% and 97%.

Discussion

This prospective cohort study shows that the results of endovascular treatment of PAA are slightly inferior to those of open repair. The primary patency rate was 77% at 2 years of follow-up. Complications occurred in 21 (37%) of the 57 treated aneurysms and included occlusions, stenoses, migrations, endoleaks, and continuous sac enlargement. Twelve stent-grafts (21%) occluded, but no patient with an occluded stent-graft needed a femoropopliteal bypass or an amputation.

The Hemobahn and the Viabahn, which were used in this series, are made of a nitinol stent with an inner lining of ultrathin (100 μm) expanded PTFE. The advantages of these stent-grafts over other designs may be that they have a high flexibility, which is necessary to cross the knee joint, and that the luminal surface is made of smooth graft material instead of irregular stent material.

A literature search of reports on endovascular treatment for PAA with commercial devices only reveals case reports and small series (Table 1).[13-21] Some of these devices, including the Cragg Endopro System 1 (Mintec, Freeport, Bahamas) which became later the Passager stent-graft (Boston Scientific, Watertown, Mass, USA), and the Corvita stent-graft (Boston Scientific, Bülach, Switzerland), were relatively stiff. Therefore, they were not ideally designed to be used in a relatively small artery such as the popliteal artery that is subject to repetitive flexion and extension. Other devices such as the Wallgraft (Boston Scientific, Natick, Mass) and the Hemobahn/Viabahn are more flexible.

An advantage of the Hemobahn/Viabahn, in our view, is that the graft - not the stent - is situated at the luminal surface. In addition, greater lengths are available. The mean covered length in our series was 20 ± 6 cm (range, 10 to 34 cm). In 70% of the cases, we used more than one stent-graft to cover the length of the aneurysm and the two landing zones, with landing and overlap zones that are each preferably 3 cm long. These long overlap and landing zones are chosen to overcome the complications of migration, which may lead to either endoleak at the landing zone or disconnection at the overlap zone. A diameter mismatch between proximal and distal landing zone is another reason to use more than one stent-graft.

Several recent studies have been published showing results of open reconstruction with a femoropopliteal bypass. In these studies, including both emergent and elective cases and treated with either venous bypasses or prostheses, 5-year primary patency and limb salvage rates were 69% to 86% and 87% to 98%, respectively.[3,4,6,8,9,22-24] The 30-day mortality was 0% to 7.7%. In some of these studies, primary patency rates were 82% to 92% for the subgroup of elective cases.[4,6,23,24] All studies, however, were retrospective and may have suffered from selection bias.

Our prospective series of endovascular repair has a 2-year primary patency rate of 77% and limb savage rate of 100% after a mean follow-up of 24 months. The estimated 5-year primary patency rate was 72%. With only three patients at risk, however, comparison with open results at this time interval is unreliable.

Persistent enlargement of the aneurysm sac has been diagnosed after open repair in ≤33% of the cases.[22,25,26] In some, enlargement was caused by within sac flow from feeding branches. No type II endoleak was found in our endovascular series and only one aneurysm increased in diameter during follow-up. No good explanation for this difference between open and endovascular repair could be found.

Forty-two percent of occlusions (5 of 12) occurred within the first month and 75% (8 of 12) within 6 months after the operation. This may suggest an influence of the postoperative antiplatelet therapy. Therefore, in analogy with the use in coronary artery bypass stenting and femoropopliteal stenting,[27] we changed the follow-up protocol after April 2003, and added clopidogrel for 6 weeks after the operation. No occlusion occurred since then in 18 PAA treated. In our study, the additional use of clopidogrel proved to be the only significant predicting factor of success at univariate analysis.

Endovascular treatment of a PAA with stent-grafts is a relatively easy, minimally invasive procedure that takes about 1 hour to complete.[11]

A critical point leading to success is the meticulous measuring of the landing zone diameters. In our practice, this was best done by a dedicated vascular technician, and controlled by means of preoperative and intraoperative calibrated angiography. Another point of attention is to avoid placing the end of an overlap zone in the bending zone of the knee, situated at the level of the upper margin of the patella. This is especially true when the distal margin of the aneurysm ends at the same level as the end of the overlap zone. In two patients, this led to a stent fracture and eventually to occlusion of the stent-graft (Table 5).
In our view, the minimally invasive character of the endovascular procedure is an advantage, especially in patients with bilateral aneurysms where operation time can be saved, which is important in a country where long waiting lists for operations exist. This minimally invasive approach may be an advantage in acute cases with critical ischemia because it avoids incisions in an ischemic leg. Moreover, in cases where occlusion of the stent-graft leads to invalidating claudication or critical ischemia, a below-knee femoropopliteal bypass is still possible. Therefore, in our hospital the endovascular procedure is the first treatment option, irrespective of the availability of saphenous vein.

Conclusions

Endovascular repair of a popliteal artery aneurysm is feasible. Patency appears slightly inferior to open repair, although most open series were retrospective studies. Recent changes to the material used and the additional use of clopidogrel may improve patency rates. To better understand the potential role of this minimally invasive technique, further studies are necessary to define the ideal indications, anatomic and prosthetic graft limitations, and the effect of anticoagulant and antiplatelet treatment. A randomized controlled trial should be undertaken to fully evaluate the endovascular exclusion of PAA compared with the standard open femoropopliteal bypass procedure and with regard to patency and postoperative complications.

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ADDENDUM TO CHAPTER 6

The following paragraphs include a discussion concerning Chapter 6[1] between Diaz and Tamashiro (Hospital Nacional Alejandro Posadas, Buenos Aires, Argentina) and our group as published in

Letter to the editor. Journal of Vascular Surgery 2005;42:1040-1041.

Diaz and Tamashiro wrote in a letter to the editor a comment to our report in the Journal of Vascular Surgery. The authors found our article to be an important contribution to the field of endovascular therapy. They mention a study on the use of dynamic angiography to identify the arterial hinge point during flexion of the knee in non-aneurysmatic popliteal arteries and establish a geometric relationship between the arterial hinge point and the medial supracondylar tubercle and between the tubercle and the upper margin of the patella in a horizontal plane.[2] The suggestion is made that knowledge of the dynamic anatomy of each patient's popliteal artery at baseline might exclude some patients from endovascular repair although they agree that clinical impact of this concept remains unclear. In addition, the authors mention the difference in range of knee flexions between different cultures which might also influence the choice for endovascular repair.

Reply to letter to the editor by Tielliu and Verhoeven.
Journal of Vascular Surgery 2005;42:1041.

We agree with Diaz and Tamashiro that the nature of individual popliteal artery flexions and patient lifestyle should be considered when recommendations such as limiting knee flexion beyond 90° are being made. This recommendation was made on the assumption that stent fractures could occur as a result of repetitive stress on the device with subsequent occlusion, as was the case in two of our patients. Both the total stented length and length of the overlap zone were not identified as predictors for failure in our series. However, the exact location of the end of the overlap zone as related to the upper margin of the patella was not investigated as a distinct factor.
Diaz and colleagues' findings of the arterial hinge point, as developed during dynamic angiography being situated at the upper margin of the patella, contribute to the better understanding of the flexion mechanism of the popliteal artery in patients with symptomatic peripheral atherosclerosis.[2] Bending zones in vessels containing an aneurysm, however, appear to be different,

affected by the extent of calcifications, and the location and diameter of the popliteal aneurysm, as shown on anteroposterior and lateral radiographs routinely made during follow-up.

In our series, stent breakage occurred in both cases at the end of an overlap zone located at the suggested hinge point at the level of the adductor tubercle of the femur, but also at the distal borderline of the aneurysm (Figure 1). Hypothetically, it may be anticipated that the closer the overlap zone is situated to the hinge point of the popliteal artery, the greater repetitive mechanical stress on the device will be at that point.

Figure 1. Radiograph of the knee in lateral projection shows three overlapping stent-grafts in the popliteal artery with fracture at the level of the proximal end of the distal overlap zone. This fracture point coincides with the level of the distal border of the aneurysm and of the adductor tubercle of the femur.

We now choose the positioning of stent-grafts more carefully, trying to keep overlap zones away from the edges of the aneurysm as well as away from the hinge point of the popliteal artery. An additional lateral view with the knee in flexion performed during preoperative angiography may increase accuracy of the procedure even more so as suggested by Diaz and colleagues (Figure 2).

Limitations to achieve maximal accuracy, however, are dictated by the available lengths of the stent-grafts.

Finally, cultural aspects may be important but did not play a role in our predominantly Caucasian study population.

Figure 2. Angiogram shows the popliteal artery in lateral projection and with the knee in 90° flexion. The hinge point of the artery is situated at the level of the adductor tubercle.

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Chapter 7

ENDOVASCULAR TREATMENT OF POPLITEAL ARTERY ANEURYSMS: IS THE TECHNIQUE A VALID ALTERNATIVE TO OPEN SURGERY?

Ignace F. Tielliu, Eric L. Verhoeven, Clark J. Zeebregts, Ted R. Prins,
Wendy T. Bos, Jan J. van den Dungen

Journal of Cardiovascular Surgery 2007;48:275-279

Introduction

Feasibility of endovascular repair of popliteal artery aneurysms (PAA) has been established.[1-3] Although no level 1 or 2 evidence is available, endovascular repair can be considered a valid alternative to open surgery in selected patients. Whether the technique should be regarded the first treatment option for all patients remains to be demonstrated. Potential long-term problems such as stent-graft migration and fractures with occlusions mandate us to be cautious in younger and active patients.
The potential advantages of the minimally invasive approach are especially attractive in older patients, patients with bilateral aneurysms, and in acute cases, where successful thrombolysis can safely be followed by endovascular repair. The endovascular technique can also be credited for reopening the discussion on best open surgical technique. Indeed, ongoing aneurysm growth due to retrograde bleeding of side branches, sometimes resulting in rupture, has been described after open medial approach with ligation of the aneurysm and a short bypass.[4-6] Therefore, some surgeons now prefer a posterior approach with complete exclusion of the aneurysm followed by a short interposition graft. This approach, however, requires a PAA that does not extend proximally of the adductor canal of Hunter.
Like other endovascular techniques, endovascular repair of PAA is bound to evolve; we have passed the learning curve and materials are improving, most probably resulting in better outcomes in the future. Finally, in our published series, the largest worldwide, occlusions did not always result in critical ischemia, and no amputation has been needed in the entire cohort.[7]
The aim of this study was to evaluate overall results in this prospective group, and to evaluate the learning curve of the technique, by analyzing the timing of occurrence of events such as occlusions and stent-graft related complications.

Materials and methods

Between June 1998 and February 2007, 89 popliteal arteries were evaluated, and 77 (87%) treated by endovascular repair. Four patients were excluded from this study. They were treated with a stent-graft for a false aneurysm after femoropopliteal bypass graft (n = 3) or an iatrogenic arteriovenous fistula (n = 1) after arthroscopy. In total, 73 PAA in 60 patients were treated by endovascular means.

Primary outcome was stent-graft patency. Secondary outcome was a combined end-point of moderate and severe stent-graft related complications, including occlusion, migration, stent-graft fracture, and stenosis.[8] Migration was defined as any migration more than 5 mm on radiograph of the knee, or requiring reintervention due to endoleak. All fractures seen on radiograph were included, but stent-graft integrity variations without clinical consequence were not (e.g. minor change of distance between two separate nitinol rings).[8] Stenosis was defined as any stenosis of more than 50% on duplex ultrasound scanning, or necessitating a reintervention to maintain patency.

Table 1. Overview of complications requiring reinterventions.

Complication	n	Reintervention
Endoleak type I *	2	Extension stent-graft
Endoleak type II †	2	Thrombin injection
Endoleak type III ‡	1	Bridging stent-graft
Endoleak type IV §	1	Ligation + open bypass
Stenosis	2 (3)**	PTA
Occlusion	11	Thrombectomy (n = 3)
		Thrombolysis (n = 4)
		Thrombolysis + stent (n = 3)
		Open bypass (n = 1)
Total	**19 (20)****	

PTA, percutaneous transluminal angioplasty

* As a result of proximal or distal migration.

† As a result of backbleeding of genicular branches.

‡ As a result of disconnection of two overlapping stent-grafts.

§ As a result of fracture and tear in the graft material.

** One stenosis required treatment twice.

During the study period, several changes of protocol were initiated. One of the changes included the introduction of a more aggressive antithrombotic protocol, including clopidogrel 75 mg daily for a postoperative period of 6 weeks, in addition to the standard daily 80 mg of acetylsalicylic acid. From the first 23 patients onwards, all patients were prescribed this regimen, except if they already were on both coumarines and aspirin for cardiac reasons. In 2003, the Viabahn (W.L. Gore & Associates, Flagstaff, Ariz, USA) became available, but only in diameters up to 8 mm. This device presented with a tip-to-hub deployment instead of hub-to-tip deployment for the

Hemobahn (W.L. Gore), thus allowing for more precise positioning distally. The Viabahn quickly became first choice in all arteries with a suitable landing zone (i.e. up to 7 mm in diameter). Another improvement based on clinical experience was the avoidance of an overlap zone between two stent-grafts at the hinge point of the popliteal artery and the end of the PAA. Indeed, the difference in compliance between a single layer stent-graft and a double layer overlap zone did result in stent-graft fractures. This was observed a few times, especially in active patients.
To study the learning curve, the cohort of patients was divided into two groups (group A from 1-23; group B from 24-73). Cut-off point chosen was the introduction of the more aggressive postoperative anticoagulation protocol with acetylsalicylic acid and clopidogrel. Indeed, in a previous study, the addition of clopidogrel proved to be the only significant factor for patency in a multivariate analysis.[7] The same end-points were used to compare both groups, i.e. occlusion, and a combined end-point of stent-graft related complications (occlusion, migration, fracture, stenosis). For the combined end-point of stent-graft complications, only one event per patient was recorded in case of multiple complications.

Follow-up

Patients were seen in the out-patient clinic every 6 months. A duplex ultra–sound examination, ankle-brachial index, and a lateral radiograph of the knee in extension and in 90° flexion were performed, as well as an antero-posterior radiograph in extension.

Statistical analysis

Data for continuous variables were expressed as mean ± standard deviation. Data were prospectively collected in a database and analyzed in a retrospective manner. Primary outcome measure was graft patency. Other studied parameters included stent-graft related complications, such as migration, fracture and endoleak, as well as reinterventions. Time-to-event variables were studied with Kaplan-Meier survival analysis using the Statistical Package for the Social Sciences (SPSS) version 14.0 software (SPSS, Chicago, Ill, USA). A P value < 0.05 was considered statistically significant.

Results

In total 73 PAA were treated in 60 patients of which 57 were men (95%) and 3 were women (5%). Mean age of the patients was 67 years (range, 51 to 94 years). Mean diameter of the aneurysms was 30 mm (range, 16 to 65 mm). Six aneurysms (8.2%) were treated emergently for acute ischemia. Mean follow-up time was 37 ± 28 months (range, 1 to 104 months).

Overall results

Eighteen (25%) stent-grafts occluded. In 7, no intervention was judged necessary because the patients presented with mild claudication only. The other 11 cases presented with acute ischemia. They were treated by thrombolysis (n = 8), thrombectomy (n = 2), or open bypass surgery (n = 1). Five stent-grafts reoccluded, all resulting in claudication, not necessitating open surgical repair. The other 5 stent-grafts are patent, with the patients symptom-free.

Migration, fracture, and stenosis was diagnosed in 9, 3 (2 leading to occlu–sion), and 2 limbs, respectively. These 14 complications accounted for reinterventions in 8 additional patients (Table 1). In total, 19 of the 73 limbs (26%) required 20 reinterventions, including 2 conversions to open repair, and 2 cases of persistent type II endoleak treated by thrombin injection.

Overall 3-year and 5-year patency rates were 77% and 70% for primary patency, and 86% and 76% for secondary patency, respectively (Figure 1).

Comparison of both groups

There were more occlusions in group A (8/23, 35%) vs group B (10/50, 20%), but this difference did not reach statistical significance (P = 0.22) (Figure 2). With regard to the combined endpoint, there were more events in group A (14/23, 61%) than in group B (16/50, 32%). In group A, there were 8 occlusions, 6 migrations, 2 fractures (both leading to occlusion, and included in the 8 occlusions), and no stenoses. In group B, there were 10 occlusions, 3 migrations, 1 fracture, and 2 stenoses. This difference was statistically significant with Kaplan-Meier analysis (P = 0.016) (Figure 3).

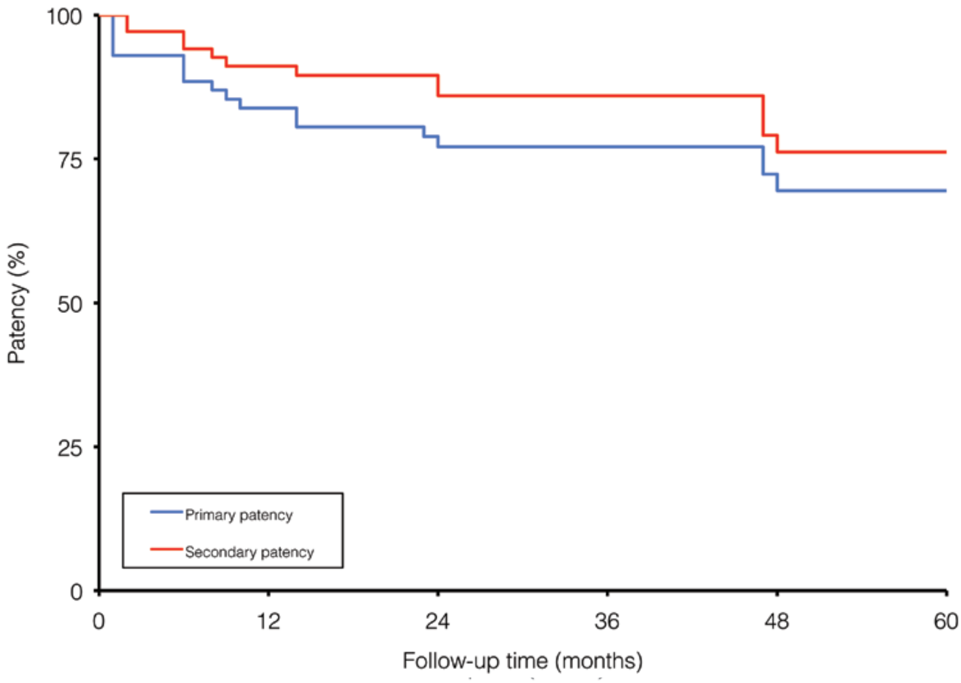

Figure 1.

Kaplan-Meier estimated primary patency rates.

Time (months)	12	24	36	48	60
Cumulative proportion (%)	83.8	77.1	77.1	69.5	69.5
Number at risk	52	43	32	24	15

Kaplan-Meier estimated secondary patency rates.

Time (months)	12	24	36	48	60
Cumulative proportion (%)	91.1	86.0	86.0	76.2	76.2
Number at risk	57	47	35	26	17

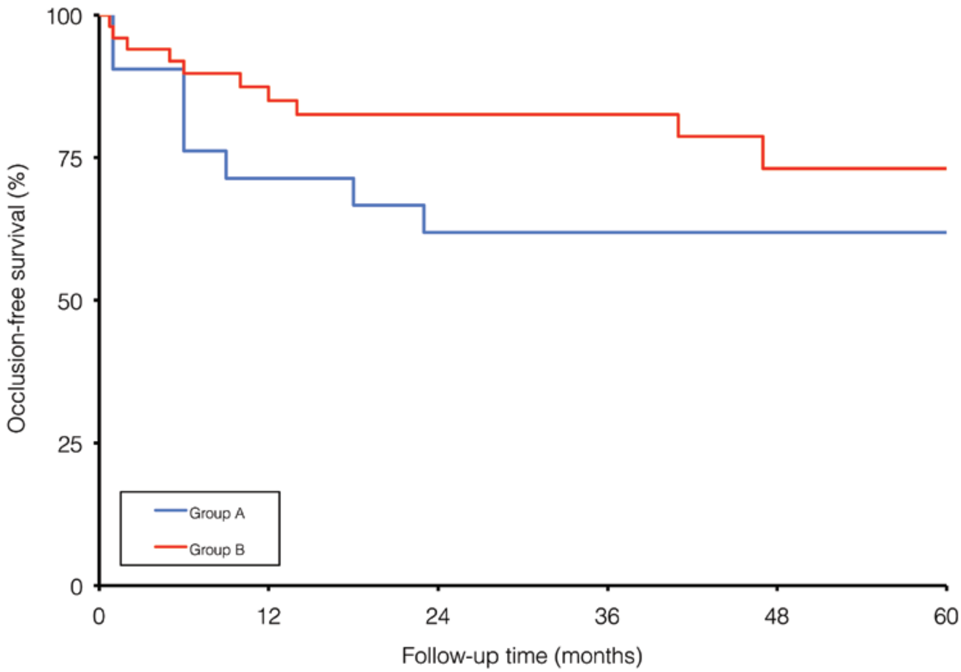

Figure 2. Kaplan-Meier estimated occlusion-free survival of stent-grafts.

Group A

Time (months)	12	24	36	48	60
Cumulative proportion (%)	71.4	61.9	61.9	61.9	61.9
Number at risk	15	13	12	12	12

Group B

Time (months)	12	24	36	48	60
Cumulative proportion (%)	85.0	82.6	82.6	82.6	73.1
Number at risk	36	30	24	12	4

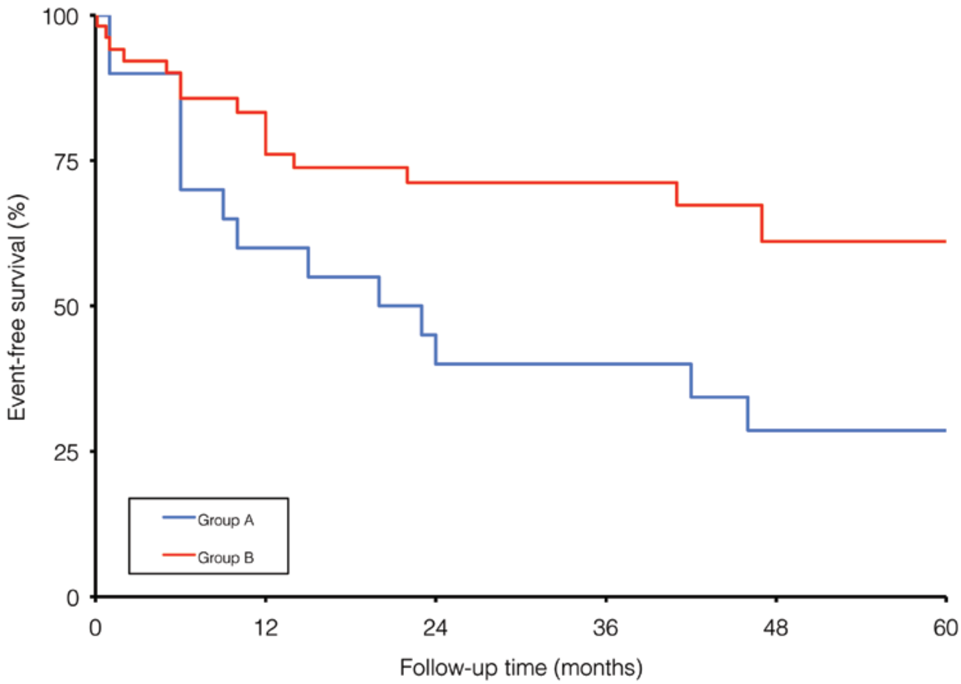

Figure 3. Kaplan-Meier estimated cumulative combined event-free survival (migration, occlusion, stenosis, stent fracture).

Time (months)	12	24	36	48	60
Cumulative proportion (%)	60.0	40.0	40.0	28.6	28.6
Number at risk	11	8	7	4	4

Time (months)	12	24	36	48	60
Cumulative proportion (%)	76.1	71.2	71.2	61.1	61.1
Number at risk	32	25	20	8	2

Discussion

With an overall primary and secondary patency rate of 77% and 70%, and 86% and 76% respectively, at 3 and 5 years follow-up, the results of endovascular PAA repair seem to be in range with open surgery. Although some articles have reported better patencies with elective open repair, one has to consider that this endovascular report includes 7 acute patients, of which six were treated with thrombolysis prior to stent-grafting.[9-13] The safety of the technique is demonstrated by the zero amputation rate in our series. Furthermore, the inclusion rate was high (73/85) thus avoiding criticism of heavy selection bias.

No randomized trial with stent-graft patency as primary end-point has been carried out to this time. The major hurdle for such a noninferiority trial is the large number of patients needed for randomization as described by Antonello et al.[14]

It is clear that all endovascular techniques need and deserve a learning curve experience before being judged too soon. Not only in terms of intraoperative technical skills, but also in view of the constant development of grafts and ancillary products. We have learned to avoid overlap between two stent-grafts in so-called critical zones. One of them is the hinge point of the popliteal artery, which is situated higher than the knee-joint, but the edges of the PAA also seem to be critical. We now do select length and position of our grafts to allow for these critical areas to be covered by a single layer of stent-graft. The change in postoperative anticoagulation protocol was dictated by published results in coronary artery stenting, and critical appraisal by colleagues and reviewers of previous publications. In addition, in our early experience, we noticed a number of early occlusions. Of the patients who did not receive clopidogrel postoperatively (n = 35), five stent-grafts occluded within one month. In comparison, in the patients who received clopidogrel (n = 38) the first occlusion occurred after 8 months postoperatively. The subgroup analysis demonstrated that the results have improved. There has been a statistical significant reduction in stent-graft related complications. With regard to occlusion alone this difference was not significant, but this is most probably due to an overly small sample size.

Nevertheless, the present study carries a number of limitations. We do have to admit a pre-selection bias, in view of referral pattern from smaller hospitals in our region. Our large experience is based on a good cooperation with these hospitals, which refer the patients for endovascular treatment, but obviously treat patients by open means locally. Therefore, our experience cannot be generalized. Another limitation that needs to be considered is the loss of quality of life in patients with an occluded stent-graft (moderate to severe claudication) in whom we decided not to reintervene on. The evolving selection criteria also have to be taken into account when interpreting this study. We now tend more and more to exclude patients with inflow disease, and young and active patients, as mentioned above. Finally, although we achieved better results after the initial learning curve, the complication rate (32%) is still high.

Conclusions

Results of endovascular repair of PAA are improving and in range with those of open repair. Therefore the choice between open repair, either by medial or posterior approach, and endovascular repair, needs to be balanced individually patient-related. This choice must be based on anatomical and patient-related characteristics. In view of our results, we continue to consider endovascular repair as a first option, except in young and active patients, in whom we prefer an open posterior approach whenever possible. Further studies are necessary to define indications, anatomical and prosthetic graft limitations, and the exact role of postoperative anticoagulation therapy.

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Chapter 8

STENT FRACTURES IN THE HEMOBAHN/VIABAHN STENT-GRAFT AFTER ENDOVASCULAR POPLITEAL ANEURYSM REPAIR

Ignace F. Tielliu, Clark J. Zeebregts, George Vourliotakis, Foppe Bekkema, Jan J. van den Dungen, Ted R. Prins, Eric L. Verhoeven

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Introduction

In 1994, the first report on endovascular repair of a popliteal artery aneurysm (PAA) was published.[1] This approach involved a standard polytetra–fluoroethylene (PTFE) graft that was inserted via the common femoral artery and secured at both ends by balloon expandable stents. Since then, flexible stent-grafts have been developed, including the Hemobahn/Viabahn (W.L. Gore and Associates, Flagstaff, Ariz, USA), and the Wallgraft (Boston Scientific Inc, Natick, Mass, USA). Both grafts have been used to treat PAA and various groups of investigators published their results.[2-9]
A recent meta-analysis compared endovascular repair of PAA to open surgery and included 3 studies and 141 patients (37 endovascular, 104 open).[10] The authors concluded that the main advantage of endovascular repair was a shorter hospital length of stay, with a weighted mean difference of -3.9 days in favor of endovascular repair. Mid-term results were similar for both treatment modalities, but 30-day graft thrombosis (odds ratio [OR] 5.05) and reintervention rates (OR 18.8) were significantly higher for endovascular repair. However, these studies also included the learning curve and therefore results have to be interpreted with caution.
It is imaginable that the use of a stent-graft across the flexible knee joint would present with a higher risk of fracture and subsequent occlusion. The reported incidence of stent fractures after popliteal stent-grafting, however, is surprisingly low.
In this study, the incidence and origin of stent-graft fractures and their impact on patency, as well as strategies to prevent them, are analyzed.

Methods

Design and objective of the study

Our endovascular PAA registry was analyzed retrospectively. The objective was to investigate the incidence and origin of stent fractures and their clinical impact. The study was based on the use of Hemobahn/Viabahn devices only.

Subjects and procedure

All PAA treated with an endovascular stent-graft between June 1998 and December 2008 were analyzed. Only true atherosclerotic aneurysms were included. False aneurysms at the distal anastomosis of three femoropopliteal bypass grafts that were treated by endovascular means were excluded from the study. Other exclusion criteria were a landing zone in the proximal and distal popliteal artery of <3 cm length; extensive aneurysmal or stenotic disease at the level of the iliac and femoral arteries; and the absence of at least one good tibial or peroneal artery serving as run-off vessel.

Threshold diameter for treatment of PAA was 21 mm in elective cases. An extensive description of the preoperative evaluation and endovascular procedure as applied in our center has been reported before.[11] In summary, patients in need for treatment of PAA received a preoperative calibrated angiogram to assess inflow and outflow vessels. Patients selected for endovascular repair underwent a duplex ultrasound (DUS) examination one day before the procedure to mark the proximal and distal landing zones (and to confirm patency of the vessel). At operation, via surgical cutdown in the ipsilateral groin and after intravenous administration of 5,000 IU of heparin, the stent-graft was introduced through a 30-cm long 12F sheath placed antegradely in the common femoral artery over a 180-cm long Amplatz Super Stiff guide wire (Boston Scientific Corporation, Natick, Mass, USA). If necessary, multiple stent-grafts were inserted with an overlap zone of ≥3 cm. Landing zones were also chosen ≥3 cm long. After balloon touch-up, completion angiography was performed.

All procedures were performed by or under the supervision of two vascular surgeons (E.V. and I.T.).

All patients received antiplatelet or oral anticoagulation therapy. Up to April 2003, antiplatelet therapy consisted of a daily dose of 80 mg acetylsalicylic acid (ASA). After April 2003, this protocol was changed and 75 mg clopidogrel was added to the administration of ASA for a period of 6 weeks after the operation. Patients who were on oral anticoagulants before the intervention, mostly for cardiac indications, continued this therapy after the operation. In these patients clopidogrel was also administered for a period of 6 weeks.

Follow-up protocol

Follow-up was performed at 1 month, 6 months and yearly thereafter at the out patient clinic with DUS examination to detect stenosis, occlusion, and endoleak. In addition, a radiograph of the knee was performed in two projections. This included an anteroposterior view with the knee in extension and a lateral view with the knee in extension and in 90° flexion. All radiographs of the knee were reviewed and analyzed specifically to detect stent fractures. In addition, the location of the fractures in relation to overlap zones of different stent-grafts and to the level of the adductor tubercle of the femur was assessed.

Definitions and endpoints

A *stent fracture* was defined as any disruption of the normal structure of the stent as diagnosed on radiograph. As a result of the absence of an existing valid method for reporting, fractures were subdivided in circumferential disruptions of the normal integrity of the stent material (Figure 1) and localized or so-called strut fractures (Figure 2). Only circumferential fractures are referred to when stent fractures are mentioned in the text. The *major hinge point* of the popliteal artery was defined as situated at the level of the adductor tubercle, which corresponds to the level of the upper border of the patella, in a plane perpendicular to the femoral axis.[12]
Endpoints for outcome of the study were circumferential stent fracture, occlusion of the stent-graft, and clinical status of the patient.

Statistical analysis

Data were prospectively collected in a database and analyzed in a retrospective manner using the Statistical Package for the Social Sciences (SPSS) version 16.0 software (SPSS, Chicago, Ill, USA). Data for continuous variables were expressed as mean ± standard deviation for normal distribution and as median with a range for skewed distribution. Differences between categorical variables were analyzed with chi square or Fisher's exact test (two-sided). Differences between continuous variables were analyzed with the Student's two-tailed test (normal distribution) or Mann-Whitney U test (skewed distribution). Time-related survival was analyzed using Kaplan-

Meier statistics. Comparison between groups was performed with log-rank analysis. A P value < 0.05 was considered statistically significant.

Figure 1. Lateral view radiograph shows a stent-graft fracture both at the upper and lower border of an overlap zone, and at the level of the adductor tubercle.

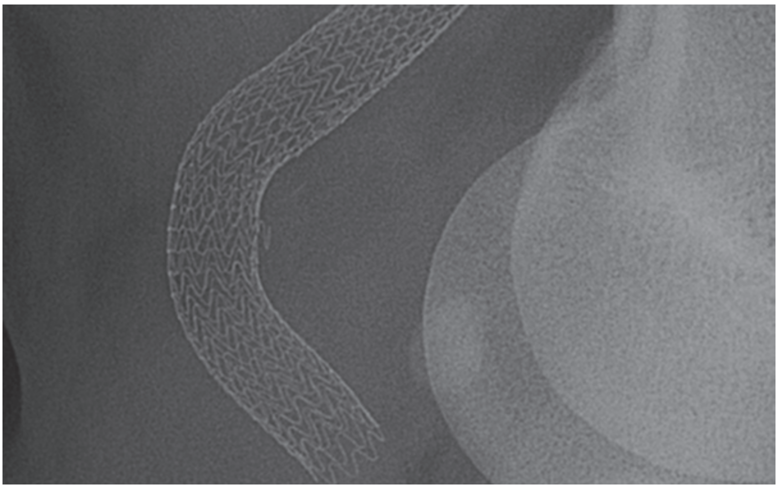


Figure 2. Lateral view radiograph shows a localized disruption of the stent-graft.

Results

In total, 78 PAA in 64 patients were treated by endovascular means. Six patients with a PAA presented with acute ischemia and were treated after successful thrombolysis. Median diameter of the PAA was 26.5 mm (range, 16 to 65 mm). Mean age of the patients was 68.6 ± 9.6 years (range, 51 to 94 years) and 61 patients (95%) were men. In 21 (26.9%) cases, a single stent-graft was used to exclude the aneurysm. In the remaining 57 (73.1%) cases, multiple stent-grafts were used (range, 2 to 4).
Mean follow-up time was 50 months (range, 1 to 127 months). Fifteen circumferential stent-fractures occurred in 13 (16.7%) cases, details of which are summarized in Table 1. In one case where a single stent-graft had been used, an endoleak was found due to disruption of the graft material. No radiograph was available to prove a stent fracture in this case. The patient underwent an infragenicular bypass in another hospital.

Table 1. Characteristics of stent-grafts with circumferential fracture(s).

			Fracture spot in relation to			
No.	**Stents, (n)**	**Fractures, (n)**	**Overlap zone**	**Adductor tubercle**	**Occlusion**	**Treatment**
1	2	1	Lower border	At tubercle	Yes	No
2	3	1	Upper border	At tubercle	Yes	No
3	2	1	Lower border	At tubercle	No	--
4	2	1	Lower border	Below tubercle	Yes	Lysis
5	2	1	Lower border	Below tubercle	No	--
6	2	2	Upper border Lower border	Above tubercle At tubercle	No	--
7	2	1	In overlap zone	At tubercle	No	--
8	2	2	In overlap Zone Lower Border	At tubercle Below tubercle	Yes	Lysis + stent (open)
9	2	1	Upper border	At tubercle	No	--
10	2	1	Upper border	At tubercle	No	--
11	1	1	NA	At tubercle	Yes	Lysis + PTA (re-occlusion)
12	2	1	Lower border	At tubercle	No	--
13	2	1	Upper border	At tubercle	No	--

NA, not applicable; *PTA*, percutaneous transluminal angioplasty.

Table 2. Influence of different variables on the occurrence of stent fractures (univariate analysis).

	Stent fracture		
	Yes (n = 13)	**No (n = 65)**	**P *value***
Patient age, mean ± SD, (years)	60.6 ± 7.3	68.4 ± 9.7	0.007
Male gender, n (%)	12 (92.3)	63 (96.9)	NS (0.426)
Total stented length, median (range) (cm)	21 (15-27)	20 (10-43)	NS (0.095)
Aneurysm diameter, median (range) (mm)	28 (23-48)	26 (16-65)	NS (0.245)
Proximal stent diameter, mean ± SD (mm)	8.5 ± 1.1	8.4 ± 1.1	NS (0.737)
Distal stent diameter, mean ± SD (mm)	8.2 ± 1.0	7.8 ± 0.9	NS (0.194)
Multiple stent-grafts used, n (%)	12 (92.3)	45 (69.2)	NS (0.167)
Calcification SFA, popliteal artery, n (%)	2 (15.4)	20 (30.8)	NS (0.330)
More than one run-off vessel, n (%)	11 (84.6)	62 (95.4)	NS (0.192)
Acute ischemia, n (%)	1 (7.7)	5 (7.7)	NS (1.000)

SD, standard deviation; *SFA*, superficial femoral artery; *NS*, not significant.

Univariate analysis to test the influence of variables on the occurrence of stent fractures revealed younger age of the patient to be a significant predictive factor (P = 0.007; mean age for the group with and without stent fracture was 60.6 ± 7.3 years and 68.4 ± 9.7 years, respectively) (Table 2). As only one significant factor was found, a multivariate analysis was not performed. A stent fracture occurred in the majority of the cases with multiple stent-grafts (14/15; 93.3%; P = 0.167). The cumulative stent fracture-free survival was estimated at 78% and 73% at 5 and 10 years follow-up, respectively (Figure 3 A).

Occlusion of the stent-graft occurred in 21 (26.9%) cases, including 5 out of 13 cases (38.5%) with stent fracture and 16 out of 65 cases (24.6%) without stent fracture. The cumulative primary patency rate, defined as time to occlusion, was not different for the fracture group compared with the non-fracture group (P = 0.284) (Figure 3 B).

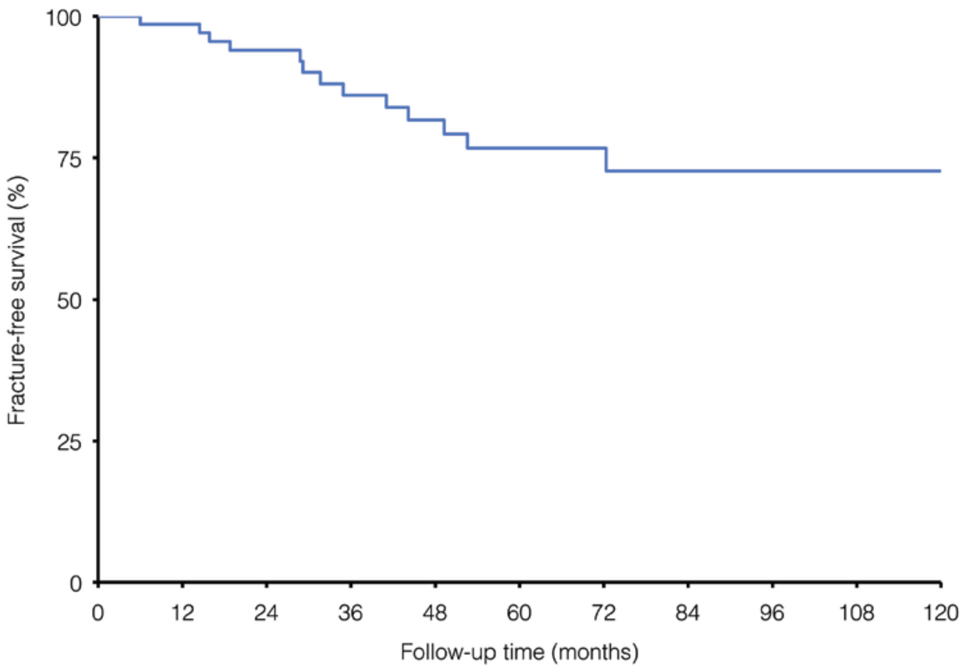
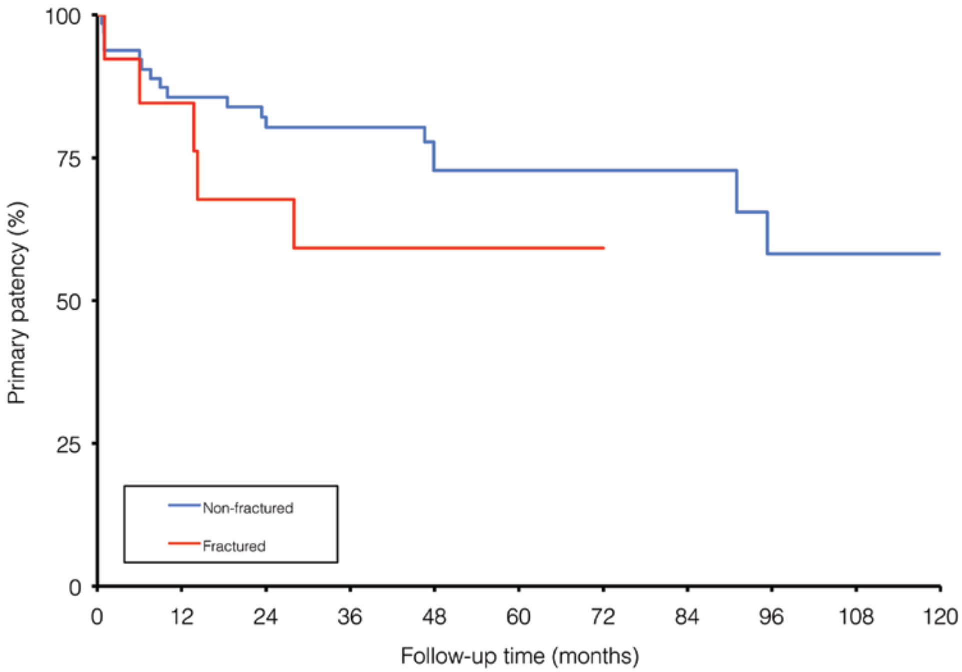


Figure 3.

A, Kaplan-Meier estimated stent fracture-free survival.

Time (months)	**12**	**24**	**36**	**48**	**60**	**72**	**84**	**96**	**108**	**120**
Cumulative proportion (%)	98.6	94.0	86.1	83.9	76.7	76.7	72.7	72.7	72.7	72.7
Number at risk	68	56	42	38	29	19	10	8	7	1
Standard Error	0.013	0.029	0.046	0.050	0.061	0.061	0.070	0.070	0.070	0.070



B, Kaplan-Meier estimated primary patency (time to occlusion).

Group without fractures

Time (months)	**12**	**24**	**36**	**48**	**60**	**72**	**84**	**96**	**108**	**120**
Cumulative proportion (%)	85.6	82.1	80.3	72.8	72.8	72.8	72.8	58.2	58.2	58.2
Number at risk	51	45	35	29	27	17	10	8	7	1
Standard Error	0.044	0.049	0.051	0.062	0.062	0.062	0.062	0.105	0.105	0.105

Group with fractures

Time (months)	**12**	**24**	**36**	**48**	**60**	**72**
Cumulative proportion (%)	84.6	67.7	59.2	59.2	59.2	59.2
Number at risk	10	8	7	6	4	1
Standard Error	0.100	0.134	0.141	0.141	0.141	0.141

Discussion

Arterial stent fractures in the femoropopliteal region have been described mainly in cases related to peripheral arterial occlusive disease. In a large prospective series with 121 cases and where different types of uncovered nitinol stents were used, Scheinert et al. reported stent fractures in 37% (45 out of 121 legs had 64 fractures), after a mean follow-up of 11 months. Stent fractures in this series included strut fractures (75%) and complete separation of stent segments (25%). Occlusion occurred in 25 of 64 (34.4%) fracture cases. A majority (67%) of the fractures was associated with stent restenosis or occlusion, and primary patency rate (defined as absence of >50% restenosis or occlusion) was significantly lower in the fractured stent group.[13] Rits et al. reviewed the literature on non-coronary arterial stent fractures and concluded that stent fractures were associated with a higher rate of reocclusion. The authors recommended detection of the fracture before clinical deterioration occurs.[14] In contrast to occlusive disease, the incidence of stent fractures after PAA repair seems to be unexpectedly low. In nine series, published since 2000 and with a total of 210 PAA included, only three fractures were described, and they were all reported in our own series from 2007[7] (Table 3). Apart from this series, regular follow-up with radiographs of the knee to detect fractures was included in the follow-up protocol in only two other series.[8,15] No stent fractures were reported in these two series. This fact may be explained in part by the lower amount of multiple stents (in 38%[8] and 57%[15] of the cases, respectively) compared with our series (73%). Another explanation may be that, in one of the two series,[15] another type of stent-graft was used (Anaconda) and the mean follow-up was only 6 months. In view of the relatively high amount of stent fractures in our series and the restricted application of radiographs in the follow-up protocols of other series, the real incidence of fractures is probably higher than suggested in the different reports. The problem of stent fractures after endovascular repair of PAA may thus be globally underestimated. In contrast to experience with stents in the femoropopliteal segment in occlusive disease,[13,14] the occurrence of a stent fracture in this study was not associated with a higher occlusion rate. Therefore, the clinical impact of stent fractures seems limited after endovascular PAA repair.

Table 3. Overview of the literature on endovascular treatment of popliteal artery aneurysms as from the year 2000 on (case reports excluded).

Author, Year	Cases, n	Type of stent-graft	>1 stent-graft, n (%)	Fracture, n (%)	FU, (months) (range) ± SD	FU protocol (imaging)
Henry,[17] 2000	12	Various *	No data	--	20.6	No X-ray
Howell,[2] 2002	13	Wallgraft	5 (38)	--	12	No X-ray
Gerasimidis,[3] 2003	9	Various †	4 (44)	--	14	No X-ray
Mohan,[4] 2006	30	Various ‡	No data	--	24	No X-ray
Rajasinghe,[5] 2006	23	Viabahn	No data	--	7	No X-ray
Curi,[6] 2006	15	Viabahn	5 (33)	--	14 ± 3	No data
Tielliu,[7] 2007	73	Hemo- /Viabahn	53 (73)	3 (4)	37 ± 28	X-ray at discharge, and every 6 months
Antonello,[8] 2007	21	Hemo- /Viabahn	8 (38)	--	47.8	X-ray every 6 months
Cinà,[15] 2008	14	Anaconda	8 (57)	--	6 ± 3	X-ray at discharge; CTA every 6 months
Idelchik,[9] 2009	33	Various§	No data	--	35.4 ± 32.1	No X-ray
This series,** 2010	78	Hemo- /Viabahn	57 (73)	13 (17)	45 (1-108)	X-ray at discharge, at 6 months, yearly

FU, follow-up; *CTA*, computed tomographic angiography; *SD*, standard deviation.
* Cragg Endopro system (7)/Corvita (3)/non-covered stent (1).
† Hemobahn (6)/Wallgraft (2)/Passager (1).
‡ Hemo- Viabahn (26)/Passager (2)/Aneurx (1)/PTFE homemade (1).
§ Wallgraft (15)/Viabahn (44).
** This series is an update of an earlier published series.[7]

Despite this, meticulous follow-up with radiographs of the knee seems warranted in view of the small study size and limited statistical impact.
Younger age proved to be a predictor of stent fracture. Mean age of the patients with stent fracture was 61 years. It is conceivable that younger patients are more active, which is reflected in a higher amount of knee flexions. Also range of motion of the knee depends on the type of activity, which is equally related to age of the patient.[16] Therefore, it is safe to advocate caution in the use of endovascular repair of PAA in younger and more active patients, although strict guidelines regarding age and activity level cannot be formulated. Also, a proof of the hypothesis that younger age yields more fractures could not be verified by analyzing fractures in bilaterally treated cases. Five out of 14 aneurysms that were treated bilaterally had a fractured stent. Three fractured unilaterally (patient age 52, 55, and 56 years) and two fractured bilaterally (age 63 and 51 years).

The majority of stent fractures in our series were situated at the border of an overlap zone (93.3%) and at the level of the adductor tubercle (73.3%). The use of multiple stent-grafts, however, was not significantly associated with the occurrence of fractures (P = 0.167). This may be attributed to a type II error as a result of limited numbers in the series. Ongoing experience with endovascular PAA repair taught us to try to avoid overlap zones at the level of the adductor tubercle. With the available Hemo-/Viabahn lengths of 10 and 15 cm, however, this proves difficult. As a result, we often end up with either the upper or the lower end of an overlap zone at the level of the major hinge point of the popliteal artery. The median total stented length in this series (78 PAA) was 20 cm, necessitating multiple stent-grafts in 73% of cases for issues of either length or discrepancy between the proximal and distal landing zone diameter. Length and diameter restrictions of the available stent-grafts have thus led to the use of multiple devices and eventually to a number of stent fractures related to overlap zones. This problem could be overcome by either using longer and/or tapered stent-grafts than currently available or by moving the overlap zone away from the hinge point of the artery. We therefore calculated that with the hypothetical availability of a 9 to 8 mm and an 8 to 7 mm tapered device with a length of 20 and 25 cm, an additional 47.4% of patients could have been treated with a single stent-graft. In addition, in the few patients still requiring two stent-grafts, the overlap zone could then be positioned far away from the crucial hinge point of the popliteal artery.

There are clearly limitations associated with this study. Only total disruptions of the stent material, defined as circumferential fractures, were studied. Localized strut fractures can only be visualized on a radiograph plane perpendicular to the fracture. As only anteroposterior and lateral views were made, the amount of strut fractures may be underestimated. Therefore, strut fractures were excluded from statistical analysis. In addition, for practical reasons, all assumptions regarding the hypothetical stent-grafts were based on data of devices that were used and not on actual duplex diameter measurements of the entire proximal and distal landing zones. Finally, this study is based on one type of device, and results should be interpreted accordingly. In our opinion, the Viabahn is still the best available stent-graft for PAA repair. It is very flexible and offers the largest variety of suitable diameters and lengths. Nonetheless, the fact that alteration of the normal stent-graft structure also occurred in a case with a single stent-graft (Figure 4) suggests that the current stent design is still not perfectly suited for this indication. More research focusing on the ideal stent design is therefore needed.

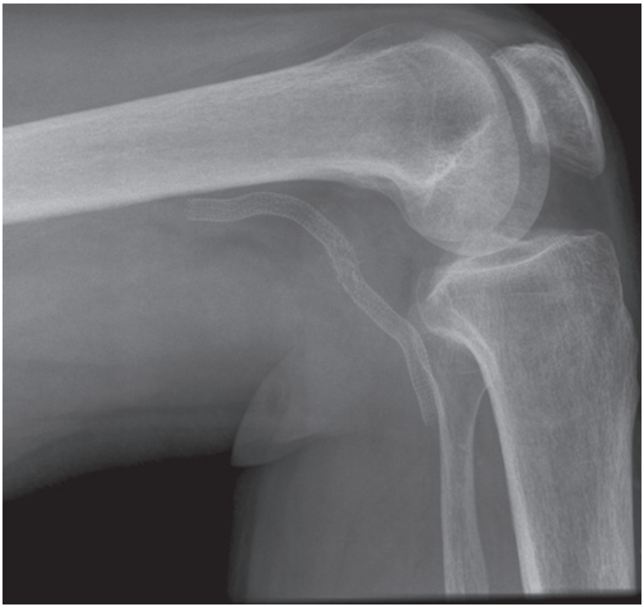


Figure 4. Lateral view radiograph shows compression of the stent material in the longitudinal axis.

Conclusions

In our series, fractures did occur after endovascular popliteal artery aneurysm repair in a considerable amount of the cases. They often occurred at overlap zones and were associated with younger age of the patient. Fracture of the stent did not influence patency of the stent-graft significantly. Further research is needed to improve the stent-graft design for endovascular treatment of PAA.

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ADDENDUM TO CHAPTER 8

During the editing process of the June 2010 number of the Journal of Vascular Surgery, the editors selected the manuscript of Chapter 8[1] entitled “Stent fractures in the Hemobahn/Viabahn stent-graft after endovascular popliteal aneurysm repair” for potential CME (Continuing Medical Education) credits from the Society for Vascular Surgery (SVS, USA).
For this purpose, two multiple choice questions were formulated to test that readers of the Journal actually read the specific article and to test whether readers understood the main conclusion of the article.
Each issue of the Journal of Vascular Surgery has 4 articles designated for potential CME credit. According to the SVS, each exam is worth 2 credit hours. An annual total of 24 credit hours may be earned. All questions must be answered correctly to obtain credit. Each exam may be retaken an unlimited number of times until successfully completed. CME questions are published online (http://www.jvascsurg.org/cme/home).

Question 1

In this series, circumferential stent fractures after endovascular popliteal aneurysm repair occurred in:

A. less than 5% of the cases
B. 5%-10% of the cases
C. 10%-15% of the cases
D. 15%-20% of the cases
E. more than 20% of the cases

Question 2

Stent fractures after endovascular popliteal aneurysm repair occurred significantly more often in cases with:

A. an overlap zone at the level of the knee joint
B. multiple stent-grafts
C. younger age of the patient
D. an aneurysm diameter >3 cm
E. a longer total stented length

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SUMMARY AND PERSPECTIVE

To introduce the reader of this thesis with some background, in **Chapter 1** a brief compilation of historical and current clinical aspects and possible solutions for the treatment of peripheral aneurysms was given. In this thesis, peripheral aneurysms are defined as aneurysms arising distally from the aortic bifurcation. Deliberately, aneurysms of the upper extremities are not discussed. They are very rare entities. An overview is given of aneurysmal disease in general and of peripheral aneurysms more specifically. Past and present treatment modalities are reviewed and an introduction to the endovascular repair is depicted.
The rationale of the thesis is outlined in **Chapter 2**. The thesis covers several aspects of the endovascular repair of iliac and popliteal artery aneurysms and these two different entities are the basis for a separation of this thesis in two sections. The iliac artery aneurysm is the subject in Section I and the popliteal artery aneurysm in Section II, respectively.

Section I
Endovascular treatment of iliac artery aneurysms

In **Chapter 3** we report the mid-term results of a prospective cohort of iliac artery aneurysms treated with tubular stent-grafts. All iliac artery aneurysms referred to the University Medical Center Groningen between June 1998 and June 2005 were evaluated for endovascular repair. Criteria for repair were a diameter of ≥30 mm for anastomotic aneurysms and ≥35 mm for true aneurysms. Preferentially, tubular stent-grafts were used as compared to bifurcated aortoiliac devices. Follow-up included both radiographs of the abdomen and duplex ultrasound examination. In 35 patients, 40 iliac artery aneurysms were treated endovascularly with a tubular stent-graft. Elective repair was performed in 30 patients (86%) and emergent repair in five patients (14%). Aneurysms were false in 26 cases (65%) and true in 14 cases (35%). Local anesthesia was used in 74% of the cases. The stent-grafts that were used included the Excluder contralateral limb (n = 28, 70%), Passager (n = 9, 22.5%), Hemobahn (n = 2, 5%), and Wallgraft (n = 1, 2.5%). The mean operation time was 83 ± 28 min (range, 50 to 150 min). Mean hospital stay was 3.3 ± 2.3 days (range, 1 to 12 days). There was no 30-day mortality. Patients were followed-up for a mean of 31.2 ± 20.7 months (range, 3 to 83 months). Complications occurred in two patients during follow-up, including migration with a proximal type I endoleak in one, and occlusion of the stent-graft in the other. The internal iliac artery was intentionally sacrificed in 28 patients (70%), and this led to gluteal claudication in three patients. As a result of this study it was concluded that the endovascular repair of iliac artery aneurysms with flexible stent-grafts is a minimally invasive technique and is associated with low mortality and morbidity. Follow-up results up to 5 years suggested that the technique is durable. It should be regarded as a first choice treatment option for suitable aneurysms.

Chapter 4 concerns the report of the treatment algorithm and the early results with the use of an iliac branched device (IBD) to preserve the internal iliac artery in the treatment of aortoiliac and solitary common iliac artery aneurysms. From September 2004 on, all patients with aortoiliac aneurysms with a suitable proximal neck or with common iliac artery aneurysms were evaluated. Selection for treatment with an IBD was done based on activity level of the patient and anatomical criteria of the aneurysm. Absolute exclusion criteria included aneurysmal internal iliac artery, severe atherosclerosis of the internal iliac artery, and small residual common iliac artery lumen. Patients who were at risk of losing one of two patent internal iliac arteries were only considered for IBD if they were physically active. Follow-up was performed with computed tomography scanning at 6 weeks and 1 year, and yearly thereafter. Fifty-nine patients (39 aortoiliac, 20 common iliac artery) were evaluated for treatment with an IBD. Seven patients were not considered for IBD for low activity level. Twenty-five patients were not suitable because of adverse anatomy. In total, 27 patients (20 aortoiliac, 7 common iliac artery) were treated with 30 IBD. Technical success was achieved in 96.3% of patients. There was no 30-day mortality. Mean follow-up period was 16.0 ± 14.0 months. In three patients the internal iliac artery side branch occluded, resulting in buttock claudication in only one patient. No external iliac artery occlusion or device component disconnection was observed. This study illustrates that an IBD provides a totally endovascular option to preserve the internal iliac artery in selected aortoiliac and isolated common iliac artery aneurysms. Anatomical application rate for the use of an IBD was 52.5% in our series.

Chapter 5 is a technical note related to the introduction and deployment of an IBD. This technique always involves the use of two parallel guide wires, including the indwelling through-and-through wire and a wire to introduce the bridging stent-graft. In this chapter we describe a technique that uses tromboned sheaths (i.e a 7F ANL1 inside a 10F Balkin sheath) for increased crossover stability and avoids problems associated with the use of parallel wires inside one sheath. In addition, reduction of the gap between the IBD and the origin of the internal iliac artery may result in a more stable position of the device.

No prospective randomized trial has been performed to compare the results of open and endovascular repair of iliac artery aneurysms. A case-controlled study of 71 isolated iliac aneurysms (19 open and 52 endo) showed that endovascular repair was associated with a lower length of stay, lower requirement for peri-operative blood transfusion, and similar medium term out–comes compared to open repair.[1] In addition, endovascular repair may be associated with lower 30-day mortality as compared to open repair.[2]
Despite the lack of clear evidence, endovascular repair is nowadays considered the preferred treatment for solitary iliac aneurysms. In cases where the aneurysm exerts compression on adjacent organs, however, open repair or at least open decompression of the aneurysm sac after endovascular exclusion, is recommended.[3,4]
The IBD has not yet been adopted by all vascular surgeons. First, there are still no clear guidelines regarding when to save one or both internal iliac arteries. Second, the endovascular technique with the IBD is still technically demanding and challenging to the vascular surgeon, it is time-consuming, and last but not least the device is expensive.
No randomized controlled trial has been carried out to compare the results of the IBD to internal iliac artery occlusion. In addition, quality of life studies have not been performed. In a retrospective study, Verzini et al. compared the results of hypogastric revascularization by branch endografting with those of hypogastric occlusion in 74 patients (32 IBD and 42 hypogastric occlusions) who were treated for iliac or aortoiliac aneurysms.[5] Technical failure was similar for IBD deployment (2/32) compared with hypogastric occlusion (2/42). Reintervention rates were similar (5/32 vs 4/42) at one year. Buttock claudication or erectile dysfunction were more frequent after hypogastric occlusion (8/42) compared to the IBD group (1/32) although the difference was statistically not significant.

Section II
Endovascular treatment of popliteal artery aneurysms

Popliteal artery aneurysms can be treated endovascularly with less peri–operative morbidity compared to open repair. To evaluate suitability of the endovascular technique and the clinical results of this treatment, we analyzed a prospective cohort of consecutive popliteal aneurysms. The results of this analysis are outlined in **Chapter 6**. All popliteal artery aneurysms between June 1998 and June 2004 that measured >20 mm in diameter were analyzed for endovascular repair. Anatomic suitability was based largely on quality of the proximal and distal landing zone as determined by angiography. Endovascular treatment was performed using a nitinol-supported expanded polytetrafluoroethylene (PTFE) lined stent-graft introduced through the common femoral artery. Sixty-seven aneurysms in 57 patients were analyzed. Ten aneurysms (15%) were excluded from endovascular repair or from any repair at all, for various reasons. The remaining 57 (85%) were treated endovascularly, of which five were treated emergently for acute ischemia. During a mean of 24 months follow-up, 12 stent-grafts (21%) occluded. Primary and secondary patency rates were 80% and 90% at 1 year, and 77% and 87% at 2 years of follow-up, respectively. Postoperative treatment with clopidogrel proved to be the only significant predictor for success. This study demonstrated that the endovascular repair of a popliteal artery aneurysm is feasible. Changes in the material used, and the addition of clopidogrel to the standard postoperative treatment with acetylsalicylic acid, may improve patency rates.

In the cohort of patients that were described in Chapter 6, complications occurred. The effect of the learning curve on the occurrence of complications was evaluated in a prospective cohort, as described in **Chapter 7**. Between June 1998 and February 2007, 73 popliteal aneurysms were treated by endovascular means. Primary outcome was stent-graft patency. Secondary outcome was a combined end-point of stent-graft related complications, including occlusion, migration, stent-graft fracture, and stenosis. To study the learning curve, the cohort of patients was divided into two groups (group A from 1 to 23; group B from 24 to 73). Cut-off point chosen was the introduction of the more aggressive postoperative anticoagulation protocol with clopidogrel. Eighteen (25%) stent-grafts occluded.

This resulted in a reintervention in 11 patients. Migration, fracture, and stenosis were diagnosed in 9, 3 (2 leading to occlusion), and 2 limbs, respec–tively. These 14 complications accounted for reinterventions in 8 additional patients. In total, 19 of the 73 limbs (26%) required 20 reinterventions. Overall 3-year and 5-year patency rates were 77% and 70% for primary patency, and 86% and 76% for secondary patency, respectively. There were more occlusions in group A (8/23, 35%) versus group B (10/50, 20%) (P = 0.22). With regard to the combined endpoint, there were more events in group A (14/23, 61%) than in group B (16/50, 32%) (P = 0.016). According to this study, the results of endovascular repair of popliteal artery aneurysms are improving and in range with those of open repair. One of the points of concern of endovascular treatment of popliteal artery aneurysms is that a stent-graft is positioned in an artery with hinge points. As a result, the stent-graft is exposed to repetitive flexion and extension movements and susceptible to material failure, especially of the nitinol skeleton.

In **Chapter 8**, the incidence and origin of stent-graft fractures after endovascular repair, its impact on patency, and strategies to prevent fractures, are analyzed. For that purpose, data of 78 atherosclerotic PAA in 64 patients were gathered in a prospectively-held database from 1998 to 2009. All radiographs were reviewed to detect stent fractures. Only circumferential fractures were included for analysis; localized strut fractures were excluded. Clinical endpoints were circumferential stent fracture, occlusion, and clinical status of the patient. Mean follow-up time was 50 months (range, 1 to 127 months). Fifteen circumferential stent fractures occurred in 13 (16.7%) patients. The majority of stent fractures (93.3%) were associated with the use of multiple stent-grafts. At univariate analysis, younger age was identified as the only significant predictor for stent fracture (P = 0.007). The cumulative stent fracture-free survival was estimated at 78% and 73% at 5 and 10 years follow-up, respectively. The cumulative primary patency rate, defined as time to occlusion, was not different for the fracture group compared with the non-fracture group (P = 0.284). The conclusion could be drawn that the incidence of stent fractures after endovascular popliteal aneurysm repair is probably underreported in the literature. Stent-graft fractures mainly occur at overlap zones and are associated with younger age of the patient. Fracture of the stent did not significantly influence patency of the stent-graft.

Up till now, scepticism remains regarding the endovascular repair of popliteal artery aneurysms, the basis of which is mainly the hinge point in the popliteal artery. Concerns about stenosis at the edges of the stent-graft also exist. Therefore, most vascular surgeons still favour open surgical treatment. Only three studies comparing open and endovascular repair for the treatment of popliteal artery aneurysms have been published. They comprise in total 141 patients (37 endovascular and 104 open) that have been entered in a small meta-analysis.[6] Thirty-day graft thrombosis and reintervention rate were more likely for endovascular repair. The postoperative length of stay was shorter in the endovascular group ($P < 0.001$). There was no significant difference in long-term primary patency.

Summarizing, endovascular techniques have gradually become in the last two decades a valuable alternative for standard open surgical repair of both iliac and popliteal artery aneurysms.
For iliac artery aneurysms, the endovascular repair with a stent-graft is now regarded the treatment of choice whenever the anatomy is favourable. A flexible and funnel-shaped device that adapts to the often tortuous anatomy of the iliac vessels is an advantage for successful outcome with regards to exclusion of the aneurysm and the prevention of postoperative occlusion of the stent-graft. The internal iliac artery is often sacrificed in treating iliac aneurysms, with significant risk for gluteal claudication or other symptoms of pelvic ischemia. To try to spare the internal iliac artery with endovascular techniques only, the iliac branched device has been developed. Benefit and complication rates on the long term of this device, however, are not clearly defined. In addition, effectiveness and quality of life studies have not been performed yet, especially to compare the results with the outcome of occlusion of the internal iliac artery.
For popliteal artery aneurysms, open surgical repair is still widely considered the standard treatment. Adoption of endovascular repair for this specific indication is increasing only very slowly. Refrains to apply this minimally invasive technique are mainly based on the dogma that stents should preferentially not be positioned crossing the hinge point of an artery. Although the literature comparing open and endovascular repair is scarce, results with regards to patency and limb salvage rates seem to be comparable. The big advantage is the reduction in morbidity as compared with open repair and it warrants further development of this technique.

Further refinement of stent-graft design, including availibility of longer lengths, contoured edges, funnel-shaped devices, increased flexibility, and low thrombogenecity will eventually establish endovascular repair as the treatment of choice for popliteal artery aneurysms in the near future.

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SAMENVATTING EN PERSPECTIEF

Ter inleiding bij het lezen van dit proefschrift wordt in **Hoofdstuk 1** een kort overzicht gegeven van de klinische aspecten van het perifere aneurysma en de verschillende behandelingsmogelijkheden. Perifere aneurysmata zijn in dit proefschrift gedefinieerd als aneurysmata die hun oorsprong vinden in arteriën distaal van de aortabifurcatie. Aneurysmata van de bovenste extremiteit worden in dit proefschrift niet behandeld omdat ze uiterst zeldzaam zijn. Aneurysmavorming in het algemeen, en de perifere aneurysmata in het bijzonder, worden besproken met de nadruk op de evolutie van de open chirurgische behandeling in de tijd. Hierbij hoort ook een korte introductie tot de endovasculaire behandeling met een endoprothese.
De rationale van de thesis wordt uiteengezet in **Hoofdstuk 2**. Het proefschrift behandelt de verschillende aspecten van de endovasculaire behandeling van het iliacale en popliteale aneurysma. Deze twee verschillende entiteiten liggen dan ook aan de basis van de indeling van het proefschrift in twee secties. In Sectie I wordt het iliacale aneurysma besproken en in Sectie II het aneurysma van de arteria poplitea.

Sectie I
De endovasculaire behandeling van het aneurysma van de arteria iliaca

In **Hoofdstuk 3** worden de resultaten op de middellange termijn weergegeven van een prospectieve cohort studie van aneurysmata van de arteria iliaca die behandeld werden met een endoprothese. Hiervoor werden alle iliacale aneurysmata die verwezen werden naar het Universitair Medisch Centrum Groningen (UMCG) in de periode tussen juni 1998 en juni 2005 geëvalueerd voor de mogelijkheid tot behandeling met een endoprothese. Iliacale aneurysmata werden behandeld als ze een diameter hadden bereikt van 30 mm (naadaneurysma) of 35 mm (waar aneurysma). Voor de endovasculaire behandeling werd bij voorkeur een buisvormige prothese gebruikt (in tegenstelling tot een endobifurcatieprothese). Voor de follow-up na de behandeling werd op regelmatige tijdstippen een röntgenfoto van de buik (buikoverzichtsfoto) en een echo-doppler (duplex) onderzoek verricht. Bij 35 patiënten werden 40 iliacale aneurysmata behandeld met een endoprothese. Dertig patiënten (86%) werden electief behandeld en vijf patiënten (14%) werden acuut of semi-acuut behandeld. Zesentwintig (65%) aneurysmata waren vals (naadaneurysma) en 14 (35%) waren ware aneurysmata. In 74%

van de gevallen werd alleen locale anesthesie toegepast. Verschillende soorten endoprothesen werden in deze serie gebruikt: de Excluder contralateral limb (W.L. Gore & Associates, Flagstaff, Ariz, USA) (n=28, 70%), Passager (Boston Scientific, Watertown, Mass, USA) (n=9, 22.5%), Hemobahn (W.L. Gore) (n=2, 5%), en Wallgraft (Boston Scientific, Natick, Mass) (n=1, 2.5%). De gemiddelde operatieduur bedroeg 83 ± 28 min (range, 50 to 150 min). De gemiddelde opnameduur in het ziekenhuis bedroeg 3.3 ± 2.3 dagen (range, 1 to 12 dagen). Geen enkele patiënt stierf binnen de 30 dagen. De gemiddelde follow-up duur was 31.2 ± 20.7 maanden (range, 3 tot 83 maanden). Bij twee patiënten traden complicaties op. Bij één patiënt verschoof de endoprothese met een proximaal type I endoleak als gevolg en bij een andere patiënt occludeerde de endoprothese. Bij 28 patiënten (70%) werd de arteria iliaca interna bewust opgeofferd met gluteale claudicatie als gevolg bij drie patiënten. De conclusie van deze studie was dat de behandeling van het aneurysma van de arteria iliaca met een flexibele endoprothese een minimaal invasieve techniek is die geassocieerd is met een lage mortaliteit en morbiditeit. Resultaten na een verloop van vijf jaar suggereren dat de techniek ook duurzaam is. De behandeling van het iliacale aneurysma met een endoprothese zou beschouwd kunnen worden als de voorkeursbehandeling indien het bloedvat daar anatomisch geschikt voor is.

In **Hoofdstuk 4** worden de vroege resultaten beschreven met betrekking tot het gebruik van een “iliac branched device” (IBD). Dit is een endoprothese voor de behandeling van een iliacaal aneurysma met een ingebouwde zij-arm voor de arteria iliaca interna. Hiermee kan de doorbloeding van de interna gevrijwaard worden bij de endovasculaire behandeling van aorto-iliacale aneurysmata of solitaire aneurysmata van de iliaca communis. In hetzelfde hoofdstuk wordt ook het algoritme voor behandeling van deze aneurysmata beschreven zoals dat in het UMCG gebruikt wordt. Alle patiënten die zich tussen september 2004 en september 2008 presenteerden met een aorto-iliacaal aneurysma met een proximale nek geschikt voor endovasculaire uitschakeling, of met een solitair aneurysma van de iliaca communis, werden geëvalueerd. Inclusie voor behandeling met een IBD was op basis van de maat van fysische activiteit die de patiënt nog ontplooide, en op basis van anatomische geschiktheid. Absolute exclusie criteria waren een aneurysmatische arteria iliaca interna, ernstige atherosclerose van de interna, en een klein residueel lumen van de communis (deel zonder thrombus). Bij de patiënten die dreigden slechts één van beide interna's te verliezen, werd alleen behandeling met een IBD overwogen indien ze een bepaald niveau van lichamelijke aktiviteit ontplooiden. De follow-up bestond uit een CT-scan na 6 weken en na een jaar na de behandeling, en daarna jaarlijks. In totaal werden 59 patiënten (39 aorto-iliacaal, 20 solitaire aneurysmata van de communis) geëvalueerd voor de behandeling met een IBD. Van deze groep werden er zeven niet geschikt bevonden voor behandeling met een IBD omwille van lichamelijke ongeschiktheid en werden er 25 afgekeurd omdat de anatomie van de bloedvaten dit niet toeliet. Zevenentwintig patiënten (20 aorto-iliacaal, 7 solitaire aneurysmata van de communis) werden behandeld met 30 IBD's. Technisch succes werd behaald in 96.3% van de patiënten. Geen enkele patiënt overleed binnen de 30 dagen. De gemiddelde follow-up duur bedroeg 16.0 ± 14.0 maanden. Bij drie patiënten occludeerde de zij-arm van de IBD en dit leidde tot gluteale claudicatie in één patiënt. In geen enkele patiënt occludeerde de iliaca externa of werd er een disconnectie gezien tussen de verschillende componenten van het modulaire systeem. Deze studie toont aan dat in geselecteerde gevallen, een aorto-iliacaal aneurysma of een solitair aneurysma van de iliaca communis, met behulp van een IBD kan behandeld worden middels endovasculaire technieken alleen. De toepasbaarheidsgraad op basis van anatomische gronden alleen bedroeg in deze serie 52.5%.

In **Hoofdstuk 5** wordt een nieuwe en alternatieve techniek beschreven met betrekking tot het opvoeren en het ontplooien van een IBD. Hiervoor zijn altijd twee parallelle voerdraden nodig. Eén voerdraad loopt doorheen de zij-arm van de IBD en loopt van de ene lies naar de andere lies en over de aortabifurcatie. De andere voerdraad komt vanuit de contralaterale lies, loopt over de aortabifurcatie, en wordt gebruikt om de bridging endoprothese (tussen de zij-arm van de IBD en de arteria iliaca interna) op te voeren. Bij de alternatieve techniek die in dit hoofdstuk wordt beschreven, wordt gebruik gemaakt van zogenaamde "trombone" sheaths waarbij twee sheaths in elkaar shuiven (7F ANL1 sheath in een 10F Balkin sheath). Dit mechanisme zorgt voor meer crossover stabiliteit (over de aortabifurcatie) en vermijdt problemen geassocieerd met het gebruik van parallelle voerdraden in één sheath. Een bijkomend voordeel is dat de IBD kan teruggetrokken worden zodat de ruimte tussen het uiteinde van de zij-arm van de IBD en de origo van de iliaca interna kleiner wordt. Dit kan leiden tot een stabielere ligging van de IBD en misschien ook tot minder kans op knikken van de endoprothese tussen de zij-arm en de iliaca interna.

Er zijn geen prospectief gerandomiseerde studies verschenen die de resultaten vergelijken van de open chirurgische behandeling van het aneurysma van de arteria iliaca enerzijds en van de endovasculaire behandeling hiervan anderzijds. In een case-controlled studie van 71 geïsoleerde iliacale aneurysmata (19 open en 52 endo) was de endovasculaire behandeling geassocieerd met een kortere opnameduur, minder perioperatieve bloedtransfusies, en een vergelijkbare outcome op middellange termijn, vergeleken met de open chirurgische behandeling.[1] De endovasculaire behandeling zou ook leiden tot een lagere 30-dagen mortaliteit in vergelijking met de open behandeling.[2] Ondanks dit gebrek aan bewijs wordt de endovasculaire behandeling van het geïsoleerde iliaca aneurysma toch algemeen beschouwd als de voorkeursbehandeling. In die gevallen waar het aneurysma drukt op omgevende structuren wordt de open chirurgische behandeling, of tenminste de open decompressie van het aneurysma na endovasculaire uitschakeling, aanbevolen. [3,4]
Het gebruik van het iliac branched device is nog niet wijdverspreid en is nog geen standaard techniek geworden die door alle vaatchirurgen gebruikt wordt. Hiervoor zijn verschillende redenen aan te halen. Ten eerste zijn er nog geen duidelijke richtlijnen die aangeven wanneer men, zonder nadelige effecten, één of beide interna's kan opofferen. Ten tweede is de techniek voor het inbrengen van een IBD complex en het blijft een technische uitdaging voor de vaatchirurg. Bovendien is de procedure tijdrovend, en vooral, het device heeft een hoge kostprijs.
Het verschil in outcome tussen het sparen van de interna met een IBD en het opofferen van de interna, is nooit onderzocht in een gerandomiseerde studie. Bovendien zijn er ook nooit quality of life studies hieromtrent uitgevoerd. In een retrospectieve studie, gepubliceerd door Verzini et al., worden de resultaten van internarevascularisatie door middel van een IBD vergeleken met die van occlusie van de interna in 74 patiënten (32 IBD's en 42 interna occlusies) die werden behandeld voor iliacale of aorto-iliacale aneurysmata.[5] De kans op technisch falen was even groot bij de IBD groep (2/32) als bij de occlusie groep (2/42). De kans op reïnterventie was ook gelijk (5/32 vs 4/42) na verloop van één jaar. De kans op gluteale claudicatie of erectiele

dysfunctie was groter na occlusie van de interna (8/42) dan na gebruik van het IBD (1/32) hoewel het verschil niet statistisch significant was.

Sectie II
De endovasculaire behandeling van het aneurysma van de arteria poplitea

De endovasculaire behandeling van het aneurysma van de arteria poplitea gaat gepaard met minder perioperatieve morbiditeit vergeleken met de open chirurgische behandeling. Om te onderzoeken wat de toepasbaarheid van de endovasculaire techniek is, en om de klinische resultaten van deze techniek te evalueren, hebben we een prospectieve cohort van poplitea aneurysmata onderzocht. De resultaten hiervan worden uiteengezet in **Hoofdstuk 6**. Alle opeenvolgende poplitea aneurysmata met een diameter >20 mm, die tussen juni 1998 en juni 2004 werden gediagnosticeerd, werden geëvalueerd voor mogelijke endovasculaire uitschakeling. Of de aneurysmata anatomisch geschikt waren voor endovasculaire uitschakeling werd grotendeels bepaald door de kwaliteit van de proximale en distale landing zone, bepaald op basis van een conventionele substractie angiografie. Endovasculaire uitschakeling van het aneurysma gebeurde door middel van een endoprothese die bestond uit een skelet van nitinol en een bekleding gemaakt van polytetrafluoroethyleen (PTFE). Zevenenzestig aneurysmata in 57 patiënten werden geanalyseerd. Tien aneurysmata (15%) werden geweigerd voor endovasculaire behandeling of voor open chirurgische behandeling omwille van uiteenlopende redenen. De overige 57 (85%) werden endovasculair behandeld en vijf daarvan werden acuut of semi-acuut behandeld omwille van acute ischemie. De gemiddelde follow-up duur bedroeg 24 maanden en hierbij occludeerde de endoprothese in 12 benen (21%). Primaire en secundaire patency rates bedroegen respectievelijk 80% en 90% na 1 jaar, en 77% en 87% na 2 jaar follow-up. Postoperatieve medicamenteuze behandeling met clopidogrel bleek de enige significante voorspeller te zijn voor het doorgankelijk blijven van de endoprothese. Deze studie toont aan dat de endovasculaire behandeling van een aneurysma van de arteria poplitea technisch mogelijk is. Verbeteringen in het ontplooiingsmechanisme van de Viabahn (W.L. Gore & Associates, Flagstaff, Ariz, USA) in vergelijking met dat van de Hemobahn (W.L. Gore), en de toevoeging van clopidogrel aan de postoperatieve behandeling met acetyl salicylzuur zouden factoren kunnen zijn die de resultaten gunstig beïnvloeden.

In de cohort van patiënten die beschreven wordt in hoofdstuk 6 treden ook complicaties op na endovasculaire behandeling van het poplitea aneurysma. Het effect van de leercurve op het optreden van die complicaties wordt geanalyseerd in **Hoofdstuk 7**. Van juni 1998 tot februari 2007 werden 73 poplitea aneurysmata endovasculair behandeld met een endoprothese. De primaire uitkomstmaat was patency van de endoprothese. De secundaire uitkomstmaat was een gecombineerd eindpunt van endoprothese-gerelateerde complicaties zoals occlusie, migratie, stentbreuk, en stenosevorming. Om de leercurve te bestuderen werd de cohort onderverdeeld in twee groepen (groep A van 1 tot 23; groep B van 24 tot 73). Het afkappunt in de tijd om de twee groepen te verdelen was het tijdstip waarop het aggressievere postoperatieve medicatieprotocol werd ingevoerd en waarbij clopidogrel aan de acetyl salicylzuur werd toegevoegd. Achttien (25%) endoprothesen occludeerden. Migratie, stentbreuk, en stenose werden gediagnosticeerd in respectievelijk 9, 3 (2 gaven occlusie), en 2 benen. Deze 14 complicaties leidden tot een reïnterventie in 8 patiënten. In totaal waren er 20 reïnterventies nodig in 19 van de 73 benen (26%). De 3- en 5-jaar patency rates waren respectievelijk 77% en 70% voor primaire patency, en 86% en 76% voor secundaire patency. Er waren meer occlusies in groep A (8/23, 35%) vergeleken met groep B (10/50, 20%) (P = 0.22). Met betrekking tot het gecombineerde eindpunt waren er meer events in groep A (14/23, 61%) dan in groep B (16/50, 32%) (P = 0.016). Deze studie suggereert dat de resultaten van de endovasculaire behandeling van het aneurysma van de arteria poplitea verbeteren in de loop van de tijd en met toenemende ervaring. De resultaten lijken bovendien vergelijkbaar met die van de open chirurgische behandeling. Een belangrijk punt van aandacht blijft dat bij deze behandeling een endoprothese wordt geplaatst in een slagader met een buigpunt. Als gevolg hiervan is de endoprothese onderhevig aan de repetitieve flexie-extensie bewegingen van het kniegewricht. Daardoor kan materiaalfalen optreden en meer bepaald van het nitinolskelet van de endoprothese.

Hoofdstuk 8 is een studie naar de incidentie en de oorzaken van stentbreuken na endovasculaire behandeling van het poplitea aneurysma. Bovendien wordt de impact op de patency bestudeerd en worden strategieën geformuleerd om die stentbreuken te voorkomen. Hiervoor werden de data van 78 poplitea aneurysmata in 64 patiënten, behandeld van 1998 tot 2009, verzameld in een prospectieve database en geanalyseerd. Alle röntgenfoto's van de knie werden opnieuw bekeken op zoek naar stentbreuken. Voor de analyse werden alleen circumferentiële stentbreuken geïncludeerd. Gelocaliseerde strutfrakturen werden geëxcludeerd. Klinische eindpunten van de studie waren circumferentiële stentbreuk, occlusie van de endoprothese, en de klinische toestand van de patiënt. De gemiddelde follow-up duur bedroeg 50 maanden (range, 1 tot 127 maanden). Bij 13 (16.7%) patiënten traden 15 circumferentiële stentbreuken op. De meeste stentbreuken (93.3%) waren geassocieerd met het gebruik van meerdere endoprothesen voor één aneurysma. Na univariate analyse bleek jongere leeftijd de enige significante voorspeller te zijn voor het ontstaan van een stentbreuk ($P = 0.007$). De cumulatieve stentbreuk-vrije overleving van de endoprothese werd geschat op respectievelijk 78% en 73% na 5 en 10 jaar follow-up. De cumulatieve primaire patency rate, gedefinieerd als tijd tot occlusie, was niet verschillend voor de groep met stentbreuken vergeleken met de groep zonder stentbreuken ($P = 0.284$). De conclusie van deze studie was dat de incidentie van stentbreuken na endovasculaire behandeling van poplitea aneurysmata in de literatuur waarschijnlijk onderschat wordt. Stentbreuken treden voornamelijk op bij overlapzones tussen twee endoprothesen en zijn geassocieerd met een jongere leeftijd van de patiënt. De stentbreuken hadden echter geen siginificante invloed op het ontstaan van occlusie van de endoprothese.

Ten aanzien van de endovasculaire behandeling van het poplitea aneurysma heerst er nog steeds een zekere weerstand die vooral gebaseerd is op het feit dat de endoprothese over een buigpunt moet geplaatst worden. Daarom verkiezen de meeste vaatchirurgen toch nog steeds de open chirurgische behandeling. Lovegrove et al. publiceerden een kleine meta-analyse op basis van drie studies die de open chirurgische behandeling vergeleken met de endovasculaire behandeling van het poplitea aneurysma. In totaal werden 141 patiënten (37 endovasculaire en 104 open chirurgische behandeling) in de meta-analyse geïncludeerd. De kans op occlusie en reïnterventie na 30 dagen was hoger voor de endovasculaire behandeling. De postoperatieve opnameduur was korter voor de endovasculaire behandeling (P< 0.001). Er was geen significant verschil in lange termijn patency van de endoprothese.[5]

Concluderend kunnen we stellen dat de endovasculaire behandeling in de laatste twee decennia geleidelijk aan terrein heeft veroverd op de open chirurgische behandeling en een goed alternatief is geworden voor de uitschakeling van zowel iliacale als popliteale aneurysmata.
Voor aneurysmata van de arteria iliaca is de endovasculaire behandeling zelfs de voorkeursbehandeling geworden bij anatomisch geschikte patiënten. De voorwaarde voor een succesvolle behandeling wat betreft kans op uitschakeling van het aneurysma en postoperatieve occlusie, is een flexibele en getaperde endoprothese die zich goed aanpast aan het vaak tortueuse karakter van de iliacale vaten.
De arteria iliaca interna wordt vaak opgeofferd bij de behandeling van een iliacaal aneurysma. Dit leidt in een significant aantal van de gevallen tot gluteale claudicatie of andere vormen van ischemie in en rond het kleine bekken. Om te trachten deze ischemie te voorkomen is het iliac branched device (IBD) ontwikkeld. Het nut van dit device, alsook de kans op complicaties op de lange termijn, zijn op dit moment nog onduidelijk. Bovendien werden studies naar kosteneffectiviteit en kwaliteit van leven nog niet uitgevoerd, en meer bepaald in vergelijking met de resultaten van occlusie van de iliaca interna.
Wat betreft het poplitea aneurysma wordt de open chirurgische behandeling nog steeds algemeen beschouwd als de gouden standaard. Weerstand om de minimaal invasieve endovasculaire behandeling toe te passen, is vooral gebaseerd op het dogma dat een endoprothese best niet over een buigpunt van een arterie wordt geplaatst. Het verschil tussen de open en endovasculaire behandeling wat betreft patency en kans op amputatie lijkt niet zo groot te zijn. De literatuur hieromtrent is echter beperkt. Het grote voordeel van de endovasculaire behandeling is dat de morbiditeit lager is dan bij de open chirurgische behandeling en dit alleen rechtvaardigt verdere ontwikkeling van deze techniek. Een endoprothese met onder andere grotere lengtes, getaperde vormen, meer flexibiliteit, en lagere thrombogeniciteit, zal er uiteindelijk toe leiden dat deze techniek de standaard zal worden voor de behandeling van het poplitea aneurysma in de toekomst.

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LIST OF CO-AUTHORS

Name and current affiliation

Eric L.G. Verhoeven, MD, PhD
Department of Vascular and Endovascular Surgery
Klinikum Nürnberg Süd
Nürnberg, Germany

Jan J.A.M. van den Dungen, MD, PhD
Department of Surgery, Division of Vascular Surgery
University Medical Center Groningen
Groningen, the Netherlands

Clark J. Zeebregts, MD, PhD
Department of Surgery, Division of Vascular Surgery
University Medical Center Groningen
Groningen, the Netherlands

Ted R. Prins, MD
Department of Radiology
University Medical Center Groningen
Groningen, the Netherlands

Björn I. Oranen, MD
Department of Surgery
Bethesda Ziekenhuis
Hoogeveen, the Netherlands

Wendy T.G.J. Bos-van Rossum, MD
Department of Surgery
Elkerliek Ziekenhuis, locatie Helmond
Helmond, the Netherlands

George Vourliotakis, MD, PhD
Department of Surgery, Division of Vascular Surgery
Hospital of Athens
Athens, Greece

Foppe Bekkema, MANP
Department of Surgery, Division of Vascular Surgery
University Medical Center Groningen
Groningen, the Netherlands

Mark M. Span, PhD
Technical Support Service, Faculty of Behavioural and Social Sciences
University of Groningen
Groningen, the Netherlands

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